September 9, 2005

MED-EL CORPORATION

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

RE: CMS-1501-P: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System (HOPPS) and Calendar Year 2006 Payment Rates

Dear Dr. McClellan:

I am writing to submit public comment on the proposed ruled indicated above on behalf of MED-EL Corporation, one of the world's three cochlear implant manufacturers. First, I must express my sincere gratitude to CMS on it's willingness to work with cochlear implant manufacturers and other stakeholder organizations towards establishing a more equitable payment for cochlear implants (APC 259), despite the well acknowledged problems within the OPPS methodology as related to tracking device costs and subsequently developing APC payment rates that reflect actual costs to the hospital.

The proposed CY 2006 payment rate of $21,739 for APC 259 represents a **fourteen percent** decrease in payment from the CY 2005 payment rate ($25,307) and creates an even greater economic disincentive to hospitals providing this procedure. Although the CY 2005 pay rate does not fully cover the cost of the cochlear technology *and* hospital facility costs, it does represent an amount that *more* accurately reflects the hospital's cost of providing this procedure. MED-EL Corporation, in collaboration with the other two cochlear device manufacturers, commissioned the Lewin Group (under separate contract), to perform an independent analysis of CMS' 2004 claims data used to develop the CY 2006 proposed pay rate for APC 259. Deeply troubled by the potential adverse impact to Medicare beneficiaries' access to this life-altering technology, I ask that CMS reconsider this payment proposal based on the findings of the Lewin analysis as presented in the attached Lewin Group report.

"DEVICE DEPENDENT APCs"

As acknowledged in the CY 2006 NPRM, CMS has experienced considerable challenges over the past 3 or 4 years related to accurate APC cost calculations for device-dependent APCs. As payment systems evolve, some degree of instability is expected. However, for device-dependent APCs in which the device cost accounts for greater than 75% of the total payment, inaccuracies in device costing has a significant adverse impact on payment. Based on the Lewin analysis, the difference between the median device cost derived from the 2004 CMS claims data ($16,408) and the weighted average industry selling price ($21,827) account for the proposed payment reduction for APC 259. When the weighted average industry selling price for the cochlear device is substituted for the median device cost determined from the claims data, the new Lewin APC payment rate ($27,192) reflects an amount that covers the device cost and associated hospital facility costs (see Tables 1-5).

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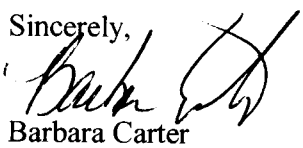
It is reported that charge compression accounts for approximately 23% underestimation of device costs. Charge compression, decrease in charges for expensive items and increase in charges for less expensive items, has a particularly harmful impact on payment for cochlear implants since the cost of the device makes up greater than 75% of the total payment. Additionally, payment for cochlear implants is severely impacted when device cost calculations are based on cost to charge ratios (CCR) with a high degree of variability. Lewin's analysis of the relationship between device charges and costs both confirm and illustrate the effects of charge compression and wide-ranging RCCs on device costs (Fig. 3, P.10). In either scenario, the extreme variance in the data makes reliance on the claims data alone problematic and leads to the establishment of an insufficient payment rate for APC 259. Therefore, CMS must accept accurate external device cost data as determined by the Lewin Group and adopt Lewin's new payment rate of $27,192, which covers the cost of the device and other hospital related costs.

The CY 2005 APC 259 payment rate of $25,307 covers the device cost and some portion of hospital facility costs. If CMS rejects Lewin's derived OPPS APC 259 payment of $27,192, respectfully, I request that CMS set the CY 2006 OPPS **no lower than 100% of the current payment rate plus the inflation and other update factors** applied to all APCs.

Otherwise, access to this life altering technology by Medicare beneficiaries will be severely impacted. Device rationing and at the extreme, closure of implant programs will likely occur if this payment proposal is adopted. Even prior to the publication of this rule, a few cochlear implant programs had terminated their programs due to poor reimbursement. Additionally, access to cochlear implants by children and non-Medicare implant candidates could be impaired since many commercial health insurers develop payment and coverage policy in accordance with CMS.

Thank you for considering the suggestions to resolving this underpayment issue which will adversely impact Medicare beneficiaries' access to technology that enables them to maintain independence, and improves their overall health and quality of life.

Sincerely,



Barbara Carter
MED-EL Corporation
Reimbursement Services

Attachment: Evaluation of the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2006 Payment Rates for Cochlear Implantation Devices, The Lewin Group, September 7, 2005

Analysis of Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for Cochlear Implantation Devices/Systems

Prepared for:

Advanced Bionics, Cochlear Americas, and Med-El Corporation

Prepared by:

Al Dobson, Ph.D.
Joan E. DaVanzo, Ph.D., M.S.W.
K. Jeannine Dollard, M.P.A.

September 7, 2005

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I. INTRODUCTION

Three years ago, The Lewin Group was commissioned separately by Advanced Bionics, Cochlear Americas, and Med-El Corporation to provide technical assistance in assessing the methodology used by The Centers for Medicare & Medicaid Services (CMS) to develop the proposed CY 2003 payment rates for cochlear implant devices/systems. The Lewin Group's initial analysis found that the proposed payment did not reflect the actual cost of the device, largely due to provider miscoding of the device. Next, Lewin recalculated the median Ambulatory Payment Classification (APC) cost by substituting a weighted average selling price that had been individually provided by manufacturers for the device cost found on the claims. Ultimately, in the Final Rule, the APC payment rate better reflected the cost of the device to hospitals as well as outpatient facility costs associated with the device procedure.

In 2004, Advanced Bionics, Cochlear Americas, and Med-El Corporation again separately commissioned The Lewin Group to replicate CMS' methodology and the proposed payment rate for cochlear implant devices/systems (APC 0259). On August 16, 2004 CMS published the proposed rule entitled Proposed Changes to the Hospital Outpatient System and Calendar Year 2005 Payment Rates in the *Federal Register*. Because hospitals had additional experience with coding under the Hospital Outpatient Prospective Payment System (OPPS) and because more data on hospital charges were available from CY 2003 claims, it was hypothesized that the proposed CY 2005 payment rate would more adequately reflect actual hospital costs for the APC. In this NPRM, CMS proposed an APC payment of $23,686 for CY 2005, with a final payment subsequently set at $25,307.

Once again, in 2005, The Lewin Group was commissioned to replicate CMS' methodology underlying the proposed payment rate for cochlear implant devices/systems (APC 0259). On July 18, 2005 CMS published a NPRM containing the proposed payment rate of $21,739 for APC 0259 for CY 2006, a fourteen percent decrease from the CY 2005 final payment rate of $25,307.

In replicating CMS' analysis of CY 2004 OPPS claims data, we found the median cost of APC 0259 to be $21,046, with a median device cost of $16,408. There is a large discrepancy between the median device cost in the CY2004 OPPS claims and the industry average selling price of $21,827. Lewin analysis of the CMS claims clearly demonstrates that the CMS proposed payment for CY2006 is not economically viable for the hospitals or the manufacturers of cochlear implant devices/systems, as it does not cover facility costs.

II. SUMMARY OF RESULTS & FINDINGS

- There is a large discrepancy between the median device cost derived from the CY 2004 OPPS claims ($16,408) and the average selling price (device list price net of discounts) of $21,827.

- CMS proposed a budget neutral, adjusted APC payment of $21,739 for CY 2006. Lewin duplicated CMS' analysis using the industry average selling price for the device and recalculated the median APC cost as $25,743, which is slightly more than the CY2005 payment of $25,307.

- The Lewin Group calculated a budget neutral APC payment of $27,192 which reflects the actual cost of the device and the hospital facility costs associated with the cochlear implantation procedure.

- The proposed payment rate for cochlear implant devices/systems is economically unsustainable, and would disadvantage Medicare beneficiaries by reducing access to cochlear implant devices/systems.

III. ANALYTIC METHODS

A. Overview

Before performing the analyses, Lewin had to create the working dataset from the CY 2004 Outpatient Prospective Payment System limited dataset of hospital outpatient claims (claims for January 1, 2004 – December 31, 2004 which were final as of July 20, 2005). To create the working dataset, Lewin applied the methodology described by CMS in the proposed rule to remove "multiple procedures" claims, leaving claims with a single APC related to CPT 69930 (cochlear device implantation). We then created "pseudo" single claims from the previously removed multiple procedure claims by applying the methodology described in the *Federal Register*.

First, bypass codes (*Federal Register*, July 25, 2005, Table 1) were eliminated from the claims. Next, date of service matching was used to create additional "pseudo" single claims. Single and "pseudo" single claims were then combined to create the APC working dataset. (See ***Figure 1*** on page 5.) To finalize the APC working dataset, non-packaged HCPCS codes (codes without a status indicator of "N") and non-packaged revenue codes (*Federal Register*, July 25, 2005, Table 2) were removed from the claims.

With the working dataset finalized, the first objective of our analysis was to determine the CY 2004 median cost for APC 0259. To estimate the median APC cost, we totaled the costs of the device and procedure as well as packaged HCPCS (codes **with** a status indicator of "N") and packaged revenue codes (*Federal Register*, July 25, 2005, Table 2) for each claim. Finally, we computed the median APC 0259 cost for all single and pseudo-single claims in our working dataset.

Our second objective was to determine the CY 2004 median cost of the device from the claims in our APC working dataset. In 2004, providers were not required to list the device separately on claims; therefore, a two step process was used to identify device costs. First, device costs for claims listing L8614 were identified. Second, on the remaining claims, we examined revenue codes 0270, 0272, 0274, and 0278 to identify additional devices that had not been separately coded. These revenue codes were selected for examination because the device, L8614, was frequently coded to these revenue centers when separately listed. (See ***Figure 2*** on page 6.) A device unit cost was computed for each claim and the median device cost was determined.

Our final objective was to recalculate the APC median and to determine a "new" budget neutral APC payment rate using a weighted average selling price (device list price net of discounts). We first calculated the weighted average selling price using confidential hospital invoice data supplied separately by each of the three manufacturers. The three manufacturers together represent 100% of the cochlear device market nationally. We then substituted the weighted average selling price for the device cost in the CY 2004 OPPS claims and recalculated an APC cost based on this information. Finally, we compared Lewin-derived APC costs (using the weighted average selling price) to APC costs derived from the CY 2004 OPPS claims. We used the median ratio to adjust the relative weight for the procedure and then calculated a "new" CY 2006 APC payment amount by multiplying the "new" relative weight by the conversion factor.

B. Detailed Methods Discussion

1. Creating the Working Dataset

Our first step in creating a working dataset was to extract all claims involving CPT code 69930 (cochlear device implantation) and/or L8614 (the device code) from among the approximately 54.6 million records in the Limited Dataset (LDS) of OPPS claims for CY 2004. This initial dataset contained a total of 962 claims. Claims that had the device L8614 coded, but did not have the corresponding CPT code for cochlear implantation, 69930, were then excluded. This created our original APC dataset, which included 939 claims.

Next, we used the methodology described by CMS in the proposed rule to eliminate multiple procedure claims and to create "pseudo" single claims from our original dataset, leaving only claims with a single APC related to CPT 69930. Two types of multiple major procedure claims were removed from the file:

- Claims in which ancillary costs cannot be associated with individual HCPCS codes because they are supportive of some or all services furnished to the patient – therefore, all claims with more than one procedure showing a status indicator of "S", "T", "V", or "X" were excluded; and
- Claims with packaged HCPCS codes coded with status indicator "N" that include more than one primary procedure (status code "S" or "T") were excluded.

In summary, in this step we extracted all of the singleton claims having only one primary procedure that could be grouped to an APC (aside from laboratory and incidentals such as packaged drugs and venipuncture). Claims could include HCPCS codes with status indicators "A," "C," "E," "G," "H," or "N," as long as there was a single primary procedure within a single APC. We also eliminated claims having a single procedure code but a zero charge. This step resulted in a dataset containing 280 true single procedure claims.

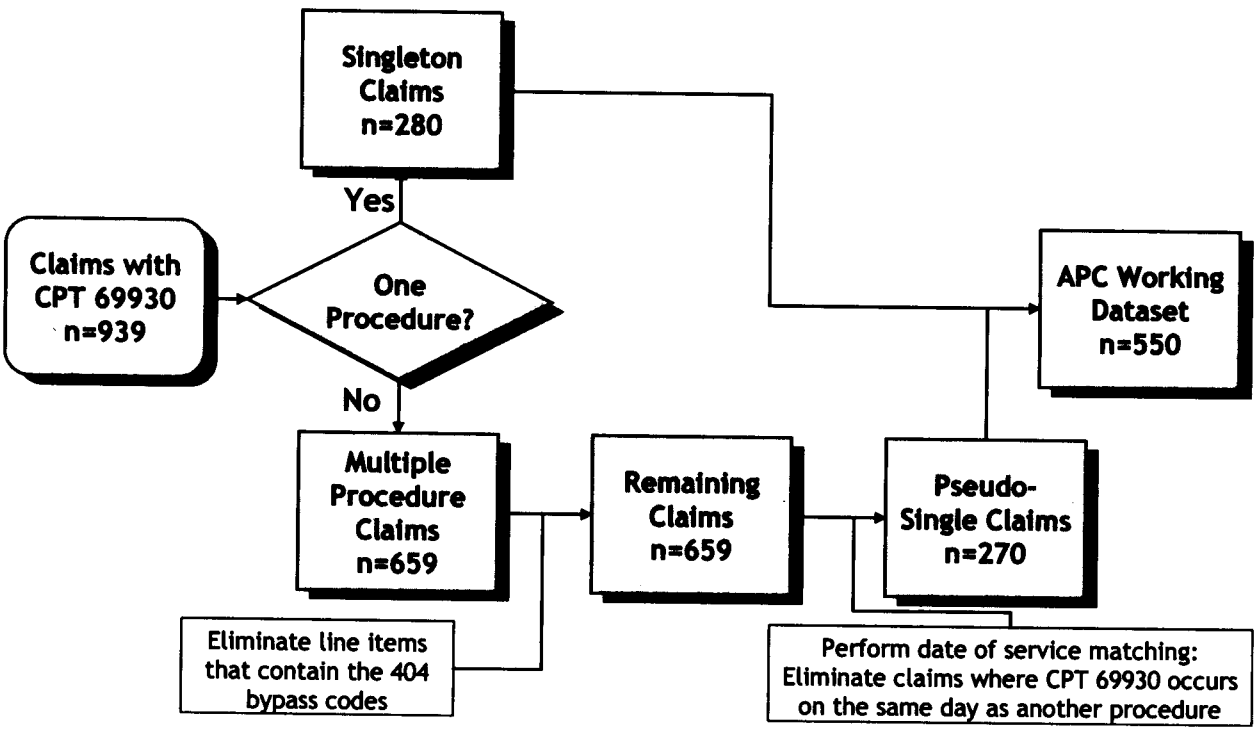
After true singletons were identified, the multiple procedure claims were evaluated to identify "pseudo" single claims. The first step in extracting "pseudo" single claims from multiple procedure claims is to eliminate line items that contain CMS' bypass codes. The bypass codes are procedure codes found to include no packaged costs and their individual costs can, therefore, be eliminated from claims with CPT 69930. Included on this list of bypass codes were chest x-ray codes (HCPCS 71010 or 71020) and an EKG code (HCPCS 93005).

Next, the dates of service were examined on the multiple procedure claims. Ultimately, "pseudo" single claims are those on which multiple procedures occur but the dates of service are different for all procedures. In this case, a multiple procedure claim would have CPT 69930 on one date of service, but different procedures on other dates of service. To create "pseudo" single claims from multiple procedure claims, the costs for the non-CPT 69930 procedure as well as any packaged costs associated with that procedure were eliminated. What remains are only the costs associated with CPT 69930. Claims could include HCPCS codes with status indicators "A," "C," "E," "G," "H," or "N," as long as there was now only a single primary procedure within a single APC.

The extraction of "pseudo" single claims from the multiple procedure claims produced an additional 270 usable claims for a combined dataset containing 550 claims. The final step was eliminating line items from the 550 claims that were not in packaged revenue centers or did not contain either the device, the procedure, or packaged HCPCs (status indicator of "N").

Figure 1 depicts the methodology employed to create the final APC working dataset.

Figure 1:
Methodology Used to Create APC Working Dataset



2. *Determining the CY 2004 OPPS Median APC Cost*

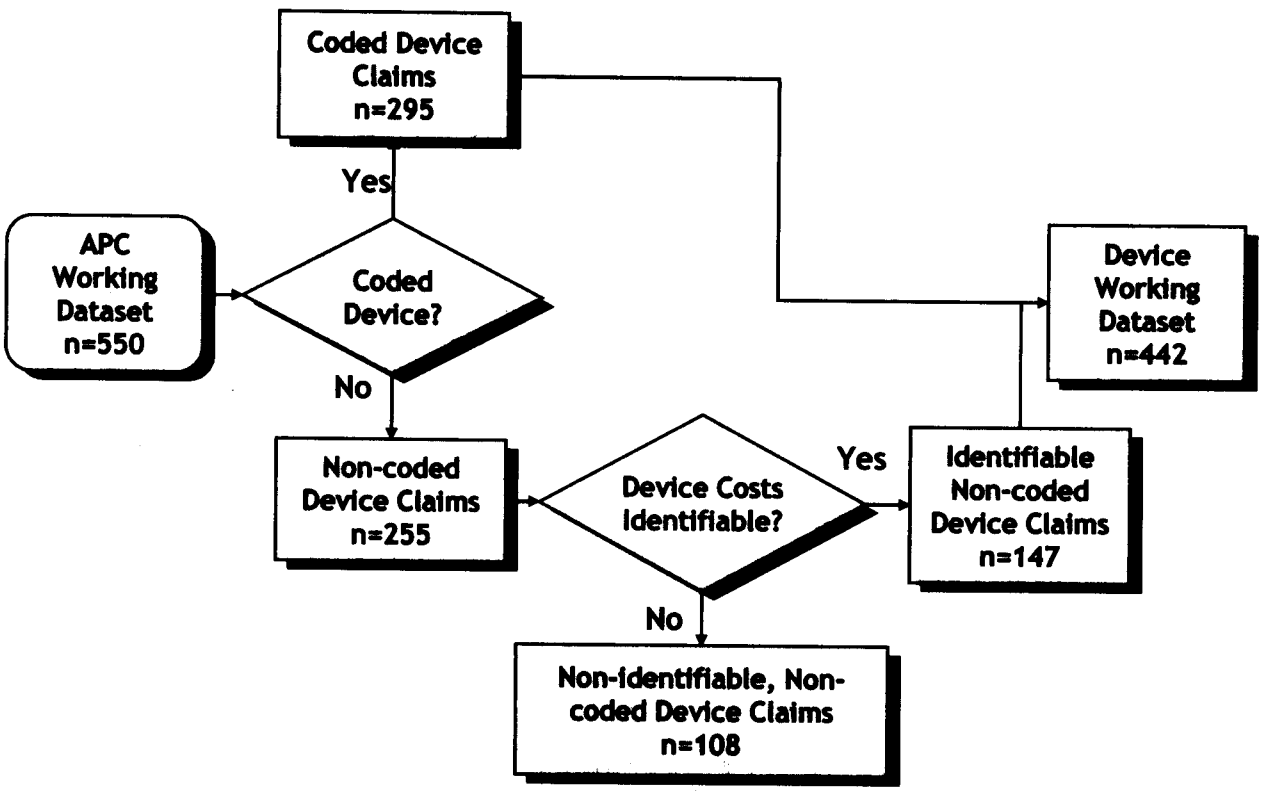
The 550 claims Lewin extracted for the APC working dataset had to include the CPT code for the cochlear implantation procedure (69930). Using this APC working dataset, we computed the APC costs for each claim. These APC costs were then converted into logs and the geometric mean was calculated. Outliers, claims with log costs that were more than three standard deviations from the geometric mean, were eliminated from the calculation of the median APC cost. Once outliers were excluded there were 544 claims in the dataset. (These results are very close to those reported by CMS; CMS reports using a total of 554 claims to calculate the APC median cost.) From the remaining claims, Lewin calculated the range, mean, median and standard deviation of the CY 2004 OPPS APC cost.

3. *Determining the CY 2004 OPPS Median Cochlear Implant Device/System Cost*

Our second objective was to determine the median cost of the device from the OPPS claims. To calculate the median device cost, only claims with identifiable device costs were used. (*Figure 2*)

The claims we kept had to include both the CPT code for the cochlear implant procedure (69930) and a device cost which could appear in revenue centers 0270, 0272, 0274 or 0278 and was or was not additionally coded L8614. Specific device costs were identified either through their HCPCS code or through revenue center designation and were used to determine the total device cost for each claim. The device working dataset included 442 claims. To calculate the median device cost, outliers were excluded based on the geometric mean and three standard deviations—this left 431 claims. Lewin then calculated the mean and median cost for the cochlear implant device/system for CY 2004.

Figure 2:
Methodology Used to Create Device Working Dataset



4. *Determining the CY 2004 Weighted Average Selling Price*

Next, Lewin calculated an actual weighted average selling price (device list price net of discounts) using confidential data supplied by the three manufacturers—Advanced Bionics, Cochlear Americas, and Med El Corporation.

5. *Calculating the CY 2004 Median APC Cost Using the Weighted Average Selling Price*

Using the results of step four above, Lewin substituted the weighted average selling price for the device cost in each claim in the device working dataset. Using the weighted average selling price, Lewin recalculated the CY 2004 median APC cost.

6. *Calculating a "New" APC Payment using a "New" Relative Weight and the CY 2006 Conversion Factor*

The final step in the Lewin analysis was to derive a "new" budget neutral CY 2006 APC payment rate. The new payment rate was derived by calculating a new relative weight and applying the CY 2006 conversion factor. To determine the new APC relative weight, Lewin first divided the APC cost calculated using the average selling price by the APC cost calculated from CY 2004 OPPS claims for each claim. This provided a ratio of these two costs for each claim. The median ratio across all claims was then identified and used to calculate a new relative weight. The "new" relative weight was then multiplied by the CY 2006 conversion factor to determine the "new" CY 2006 APC payment rate.

IV. RESULTS

Tables 1 - 4 below summarize the results of our analyses of the CY 2004 OPPS claims for the cochlear implant device/system.

A. Primary Results

In our analysis, we found the CY 2004 OPPS median APC cost to be $21,046, with a mean of $25,706 and a standard deviation of $20,760.[1] For the implant device, we found a median device cost of $16,408 in CY 2004, with a mean device cost of $20,684. See *Table 1.*

Table 1:
Results of the Lewin Group Analysis of CY 2004 OPPS Claims

	APC Cost N = 544	Device Cost N = 442
range	$1,563 - $152,934	$1,839 - $138,506
mean	$ 25,706	$ 20,684
median	**$ 21,046**	**$ 16,408**
standard deviation	$ 20,760	$ 17,087

Tables 2 and *3* contain the weighted average selling price as well as the results of the Lewin analysis using the weighted average selling price of the device. The weighted average selling price for the device is $21,827 and when this selling price is substituted for the device cost listed in the OPPS claims, the new median APC cost is $25,743.

Table 2:
Weighted Average Selling Price

Weighted Average Selling Price	$ 21,827

Table 3:
Lewin Group Analysis Using Weighted Average Selling Price

	APC Cost N = 431
range	$22,692 - $51,913
mean	$ 27,393
median	**$ 25,743**
standard deviation	$ 6,054

1 Lewin Group analysis of CY 2004 OPPS claims

To compute the "new" Lewin payment rate, first the ratio of the average selling price-based APC cost and the OPPS APC cost was calculated for each claim. The median of these cost ratios is 1.25 (***Table 4***). Also, shown in ***Table 4*** is the CMS proposed relative weight and the "new" Lewin APC relative weight.

Table 4:
Data Used to Calculate the "New" Lewin APC Payment Rate

Median of Claims Cost Ratios Avg Selling Price APC Cost/OPPS APC (a)	2006 Proposed Relative Weight (b)	"New" Lewin Relative Weight (c) = (a) * (b)
1.250825	366.3317	458.2168487

To determine the "new" Lewin-derived APC payment found in ***Table 5*** below, the "new" Lewin APC relative weight is multiplied by the CMS 2006 conversion factor of 59.343. The "new" Lewin APC payment rate is $27,192.

Table 5:
CMS Proposed CY 2006 APC Payment Rate vs. "New" Lewin APC Payment Rate

	Proposed CY 2006 Payment Rate	"New" Lewin CY 2006 Payment Rate
2006 APC Payment Amount	$ 21,739	$ 27,192

B. Other Results

In addition to performing the analyses described above, The Lewin Group used the dataset of 544 claims to identify the following data inconsistencies:

- The median CY 2004 OPPS APC cost for claims with a coded device differed from claims without a coded device. For claims with the code L8614 affixed, the median APC cost for the claims was $21,460 while the median APC cost for claims without a coded device was $19,622 (a difference of $1,838). The means for these two categories of claims exhibit a greater discrepancy, $28,108 for claims with a coded device and $23,051 for claims without a coded device - a difference of $5,057.

- For claims in which the device was coded (N=295) the median device cost was found to be $16,408 when outliers were excluded. This is different than the median device cost calculated from claims that did not have the device itself coded. For claims which did not have coded devices, we identified device costs on 147 claims. All of these claims had non-coded device costs/charges linked to revenue center 0278. These 147 claims were then used to calculate the median device cost for non-coded devices. The result was a median device cost of $15,302—a difference of $1,106 ($16,408 vs. $15,302).

- One provider submitted thirteen claims in which device L8614 costs were assigned to revenue center 0272 (medical/surgical supplies-sterile supply). Other providers submitted a total of four claims in which device L8614 costs were assigned to this revenue center.

Additionally, there were a total of 43 claims with the device coded that were assigned to revenue center 0274. A total of 60 claims with the device coded were assigned to the incorrect revenue center. (*Appendix A*)

- Providers also coded the procedure incorrectly. One provider submitted six claims for CPT 69930 in which the costs/charges were assigned to revenue center 0490 (ambulatory surgical care – general). A total of 19 claims were assigned to revenue center 0490. A different provider submitted five claims on which CPT 69930 was listed, but linked to revenue center 0369 (operating room services – other). In total 32 claims were submitted in which the procedure was linked to an incorrect revenue center. (*Appendix A*)

- One possible result of educational efforts concerning proper coding was that all providers who actually listed the device on the claim also properly coded the procedure with 69930. (*Appendix B*)

- In addition to analyzing the CY 2004 OPPS claims, we also built two tables which compare costs for CY 2004 OPPS claims to costs for CY 2003. One chart presents costs by CPT and the other displays costs by revenue center. One remarkable difference is the change in median cost, before removal of outliers, for L8614 from CY2003 to CY2004 from $22,339 in 2003 to $17,135 in 2004. (*Appendix C*) [Note that with outliers removed, the median device cost was $16,408.]

- Also notable is that in nearly all instances, the median for revenue centers associated with cochlear implants have declined. (*Appendix C*)

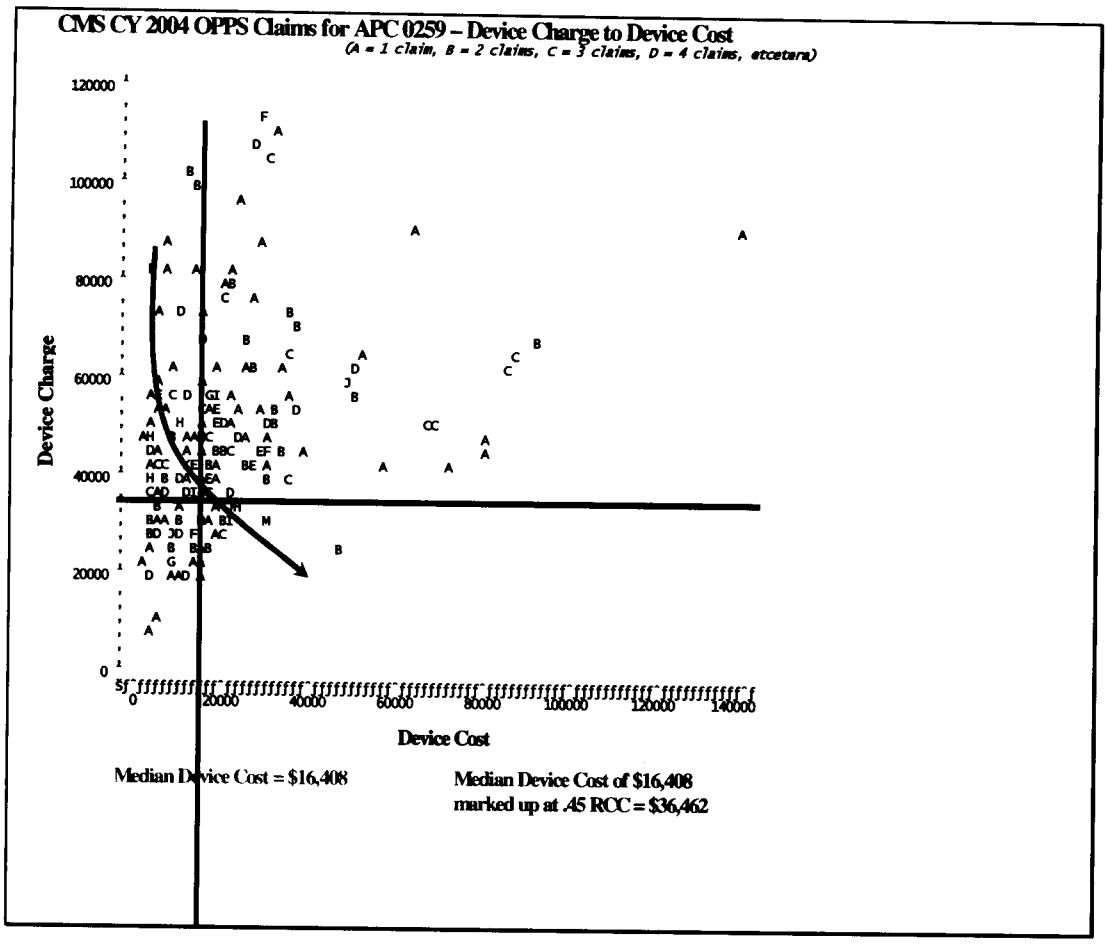
Analysis of Charges vs. Costs

In an attempt to understand the relationship between the charges and costs on the claims, we examined each of approximately 20 percent of the individual claims. We found numerous instances in which charges and costs diverged significantly (e.g., claims with charges of nearly $28,000 and costs of approximately $7,000). We also found numerous claims in which the cost was significantly higher than the charge (e.g., costs of $80,000 and charges of approximately $67,000).

We calculated the ratio of cost to charges (RCC) for each claim. We found that the RCC ranged from 0.043 to 1.769, with a mean RCC of 0.445. Because each revenue center has its own RCC, assignment of the device to the appropriate revenue center is critically important. (As noted in the section above, 60 claims had the device in the wrong revenue center.)

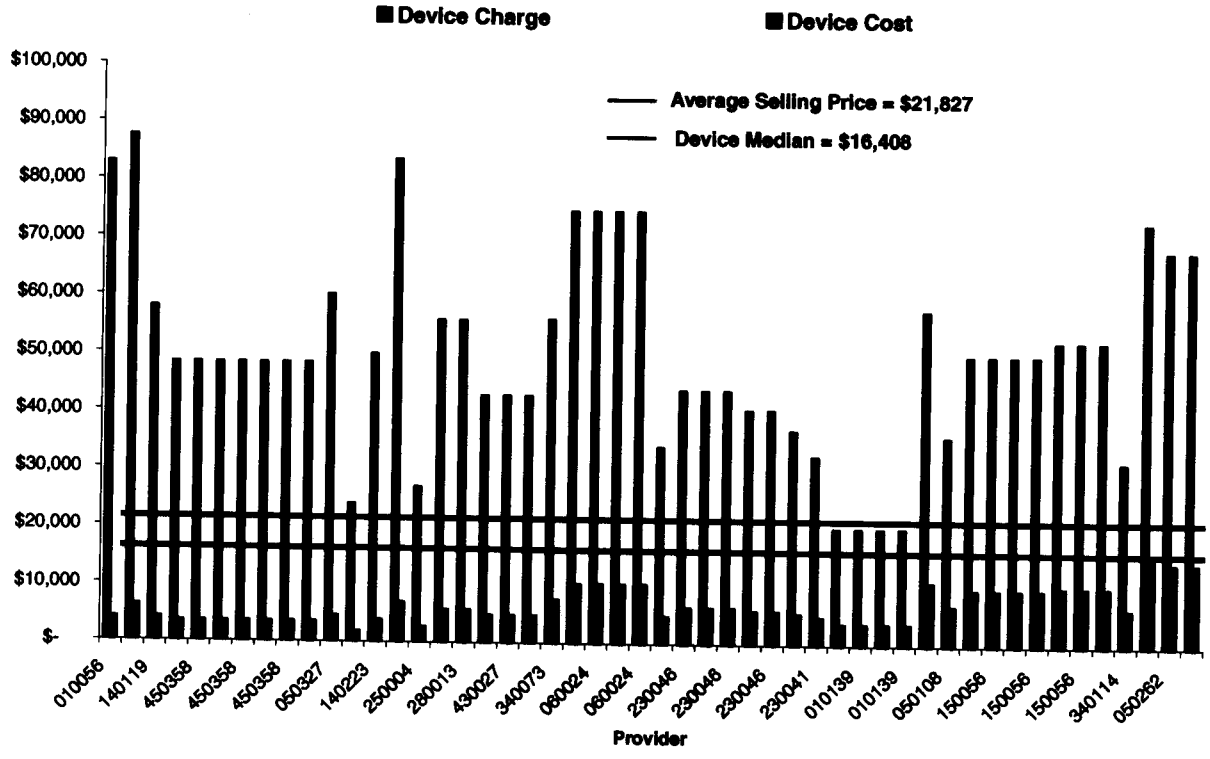
We then multiplied the CMS median cost of $16,408 by the mean RCC, obtaining a corresponding charge of $36,462. We plotted the charges vs. costs to create a picture of the distribution. (These are contained in Figure 3 below.) The large number of claims in which the device cost is low relative to a high charge for the device (claims to the left of the red line indicating the median device cost) indicates a low RCC.

Figure 3: Charges vs. Costs

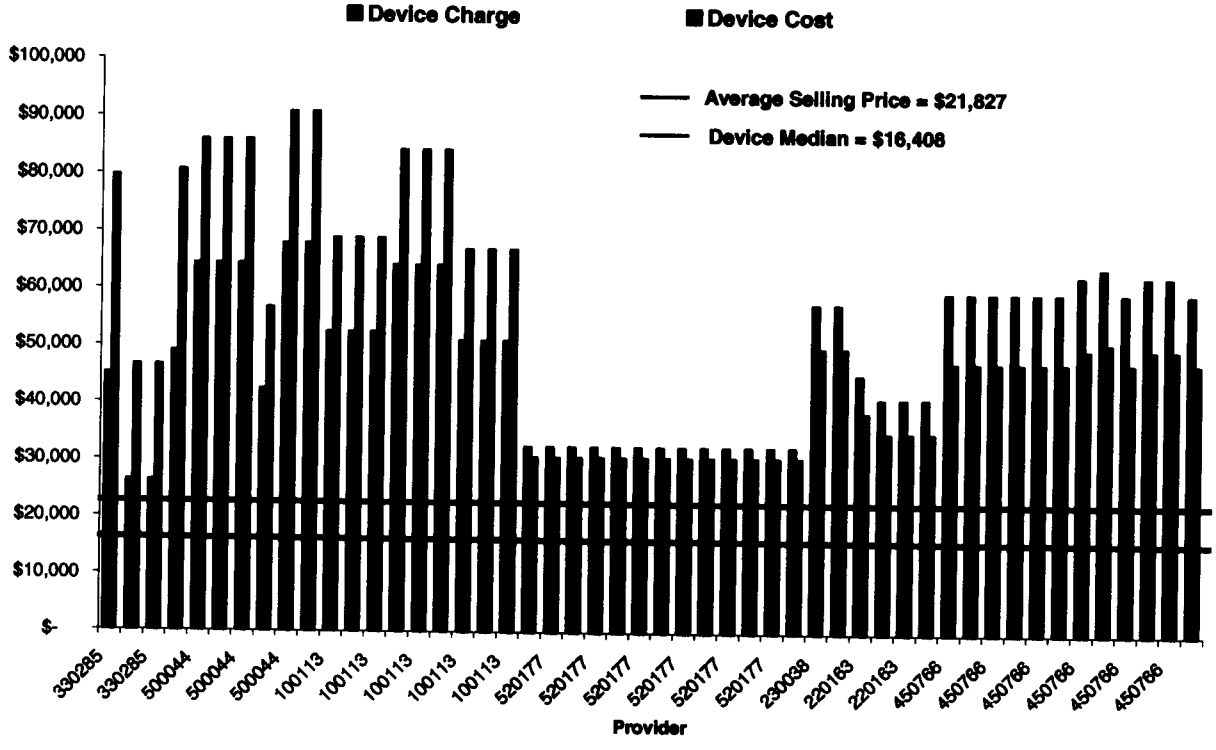


We then plotted the 50 claims with the widest divergence between charges and costs (lowest RCC) as well as the 50 claims with the highest RCC. These distributions are below, and show the extreme variance that these data contain, precluding their being used as the sole source of data for determining the cost of the device. A median cost from these data will not be reflective of the actual cost to hospitals of this device.

CMS CY 2004 OPPS Claims for APC 0259 with Device L8614 - Extreme Lows for RCC



CMS CY 2004 OPPS Claims for APC 0259 with Device L8613 - Extreme Highs for RCC



C. Discussion

The 2002 and 2004 Lewin analyses identified that the proposed CY 2003 APC and proposed CY 2005 APC payment rates were not set high enough to cover the cost of the cochlear implant device alone. This was thought to be largely due to provider coding errors which were attributed to the newness of the OPPS system and changes in pass-through payment methodology. Now that the OPPS system has been in place for several years, it was hypothesized that CMS' calculated payment rates would more accurately reflect hospital APC costs because a greater number of the claims would be correctly coded.

While hospital coding has improved, this year's study demonstrates that the proposed APC payment does not cover the cost of the device, leaving no funds for the hospital to cover facility service costs related to the procedure. The proposed APC payment rate, $21,739, is $88 less than the weighted average selling price (manufacturer's price net of discounts) of $21,827 for the device. Had the median device cost reflected the weighted average selling price of $21,827 the CY 2006 APC payment would have provided funds to cover the cost of other hospital services associated with the procedure. The "new" Lewin derived OPPS APC 0259 payment rate of $27,192 would more accurately reflect the cost of the device and would maintain the implicit facility cost of the procedure of $5,365 ($27,192 - $21,827).

In the final CY 2005 OPPS regulation, CMS set the APC rate for 0259 at $25,307. The weighted average selling price for the cochlear device was $22,350, which comprised a more economically viable situation in that the APC payment covered some portion of the hospital facility costs as well as the cost of the device.

The proposed CY 2006 payment being **less** than the average selling price of the device is untenable for both the hospitals and the manufacturers. This payment level jeopardizes access to the cochlear implant device by Medicare beneficiaries, disadvantaging all of those Medicare beneficiaries who could benefit from implantation.

Lewin has calculated a budget neutral 2006 APC rate of $27,192, which is an eight percent increase over last year's final payment of $25,307. At this level, the payment would cover the cost of the device ($21,827) and leave roughly $5,000 to cover hospital facility costs associated with implantation of a cochlear device.

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SCOD/A/D Ahmed Kane Somrow Hart Bazell

To Whom It May Concern:

The proposed rule CMS-1501-P "Medicare Program, Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" contains errors. The proposed reimbursement rates are 30% below the selling price of both Apligaf and Dermagraft. In my opinion reimbursement at this rate would jeoporadize patient acess to these products and have a very negative impact on the quality of care. I petition CMS to correct the error in the proposed ruling.

Your cooperation in this matter is greatly appreciated.

Dr. James Blaine
Podiatric Physicain &Surgeon

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Cryo

Heyster
Kane
Snow
Hart
Bazell

September 4, 2005

Mark B. McClellan, M.D., Ph.D.
Center for Medicare & Medical Services
Dept. of Health & Human Services
Attn: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Dear Sir:

I have had cryo surgery as of March 7, 2005. I believe it would be very bad to discontinue payment on this procedure to the hospitals. Since I only had half my prostate removed by cryo I could not have had this with the removal by regular invasive surgery. There are less complications and very quick recovery and no hospital stay as it was done outpatient and this made the charges way less than if I would have had a hospital stay with the regular procedure. I am fine now and back to normal with no side effects. Please do not take this away for payment as I would hate to see future men not be able to have this surgery because Medicare would not allow for payment. I would like to see more hospitals to offer it. Instead, the inadequate payment rate for 2006 will mean that there will be fewer hospitals offering it.

I am responding to a notice in the July Federal Register that contained the proposed hospital outpatient payment rates for prostate cryosurgery procedures in 2006 and I was informed that the new proposed rate will not cover what the hospital costs are.

I urge you to keep in mind the amount of future men that will need this type of surgery and I will speak for many of how good the procedure is and a lot cheaper to perform than regular removal of the prostate.

Sincerely,
Darryl G. Garbars
Darryl G. Garbars
11705 S. Derby Ln.
Plainfield, IL 60585

Cc: James L. Hart, CMS
Mary Syiek, Endocare

ASNR

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86

Timings

Burley
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Sparrow
Hart
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Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4–26–05,
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Proposed Reimbursement Changes in the Hospital Outpatient Prospective Payment System for Magnetoencephalography (MEG)

Dear Mr. McClellan,

The American Society of Neuroradiology (ASNR) represents over three thousand physicians specializing in the diagnosis and treatment of neurological diseases. The specialty is internationally recognized as a leader in the anatomic and functional imaging of the brain, using a variety of technologies including magnetoencephalography (MEG). The ASNR supports the August 18, 2005 CMS decision to defer adjustments in the level of reimbursement for MEG until accurate billing data is available. Furthermore, the society strongly supports maintaining the current level of reimbursement. These values realistically address the expenses associated with MEG examinations and should be sustained.

Access to care: The ASNR is concerned that reductions in reimbursement for clinical MEG would compromise the financial viability of existing facilities and would severely curtail the development of new MEG programs. MEG is an essential component of the pre-surgical evaluation of patients with intractable epilepsy and has a proven value in mapping the cerebral cortex prior to resection of tumors and vascular lesions such as arteriovenous malformations. A payment reduction of this magnitude would have detrimental effect on patient's access to this technology, which reduces the morbidity associated with epilepsy surgery and tumor resection. Although the number of claims filed with Medicare over the last few years has been low, Medicare is still regarded by other payer groups as the reimbursement standard; therefore a much larger patient population would be affected by the negative consequences of payment reductions for MEG.

Accuracy of data: CMS's APC advisory panel clearly recognized the limitations of current data regarding MEG charges and utilization. We enthusiastically support the recommendation for additional data gathering prior to any decision regarding reimbursement. Several MEG programs have already started the process of identifying appropriate billing information for future reviews.

We are especially concerned about the proposed $674 reimbursement for CPT 95965 (Epilepsy/Spontaneous Recording and Analysis), which was previously $5,250. The MEG instrument plus its mandatory magnetically-shielded room costs about $2.5 million dollars,

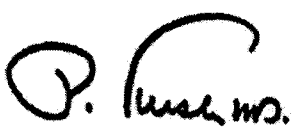
which is significantly more than many MRI scanners. Additional operational costs such as initial siting costs ($300,000+); liquid helium costs ($30,000/year), and maintenance contract for the instrument ($120,000/year) are fixed costs. MEG patient throughput is much less than other modalities because much more detailed information must be obtained by MEG. It requires about 20 hours of data analysis by the MEG scientist to fully identify and localize the sources of epileptic spikes within a patient's brain (CPT 95965); as well as about an hour to analyze and pictorially summarize the data from MEG pre-surgical mapping of such brain functions as vision, hearing, motion of hand or foot, language, etc. (CPTs 95966, 95967). In comparison, processing the images of clinical MRIs is automated and virtually instantaneous, and clinically reading these images is relatively fast.

Moreover, each scanning session in the MEG requires about one hour for each modality of pre-surgical functional data acquisition (CPT 95966 and 95967); and about four hours of data acquisition for epilepsy interictal spike generation, measurement, and monitoring.

Summary comment: There is great value to performing MEG studies, which justifies the current level of reimbursement. MEG is the only non-invasive technique which can so accurately localize interictal spikes in epilepsy; and which directly images the active brain cells responsible for vital human functions such as hearing, vision, hand motion, etc. This information is extremely valuable to the neurosurgeon; who seeks to remove a brain tumor, vascular malformation, or abnormal brain tissue responsible for seizures; because it allows him/her to avoid devastating outcomes that would result from resection of the adjacent functional brain tissue. The current charges for these three MEG CPT codes are appropriate when compared to the actual costs of performing the studies.

Sincerely,

Patrick A. Turski, MD
Chair, ASNR Clinical Practice Committee



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B-Therapy

Lovi
Kane
Snow
Hart
Bazell

September 8, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Proposed Changes to the OPPS Payment System and 2006 Payment Rates

Issue: New Technology APC

Dear Dr. McClellan:

Mentor Corporation is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

Founded in 1969, Mentor Corporation is a leading supplier of medical products for the global healthcare market. The Company develops, manufactures and markets innovative, science-based products for the aesthetics, urologic specialties and clinical and consumer healthcare markets around the world.

The Company's Aesthetics franchise includes prosthetic mammary implants for breast augmentation and reconstruction, and lipoplasty products for body contouring. Mentor's Urologic Specialties franchise includes surgical slings for the treatment of urinary stress incontinence, brachytherapy seeds for the treatment of prostate cancer, prosthetic implants for the treatment of erectile dysfunction and disposable surgical urology implants. The Company's Clinical and Consumer Healthcare franchise includes catheters and other products for the management of urinary incontinence and retention. Mentor continues to launch important line extensions to its existing products that add value to doctors and patients.

Mentor employs approximately 2000 people around the world and is headquartered in Santa Barbara, California, with manufacturing and research operations in the United States, France, the Netherlands and the United Kingdom.

We would like to thank CMS for the opportunity to make recommendations regarding the brachytherapy correctly coded claims and the CMS proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

Brachytherapy

Given the proposed reduction in 2006 payments for all brachytherapy APCs (312, 313 and 651), we recommend that CMS use only correctly coded claims for rate-setting

purposes. We urge CMS to use the most accurate and representative data possible to establish these rates by only using claims data where each brachytherapy procedure claim contains an appropriate brachytherapy source device "C" code(s). It appears that non-representative claims have a significant impact on the rates for these APC payment rates.

The 2006 HOPPS proposed payment rates are based on hospital outpatient claims from calendar year 2004. A correctly coded claim must include both a brachytherapy procedure code and a brachytherapy source device "C" code. The table below indicates the number of correctly coded claims. For this analysis, a single-procedure claim was "correctly coded" if the original claim from which it was created had the proper brachytherapy source "C" code on the claim.

Correctly Coded Brachytherapy Claims

APC	Total All Claims	% Correctly Coded Claims	Total Single Claims	Total Correctly Coded Single Claims	% of Correctly Coded Single Claims
312 Radioelement Applications	882	38%	363	46	12.7%
313 Brachytherapy	7,156	34%	8,625	3,442	39.9%
651 Complex Interstitial Radiation Source Application	11,963	86%	342	181	52.9%

When the median costs of all single procedure claims were compared to the median costs of correctly coded single procedure claims it was determined that claims that had both the brachytherapy procedure and a brachytherapy source "C" code had median costs that were 9-34% higher than the average all single-procedure claims for the APC.

CMS's coding screen for "device-dependent" APCs provides a model for examining these brachytherapy claims. CMS found that claims without a device "C" code tend to underreport charges and costs when compared to claims with the device code appropriately reported (see table below).

Comparison of Median Cost of Single Claims vs. "Correctly Coded" Single Claims

APC	Median Cost of Single Claims	Median Cost of "Correctly Coded" Single Claims	Percentage Difference of Median Cost
312 Radioelement Applications	$301.91	$403	33.5%
313 Brachytherapy	$776.35	$849.39	9.4%
651 Complex Interstitial Radiation Source Application	$732.86	$864.54	18.0%

CMS screened out these unrepresentative claims for device-dependent APCs prior to calculating the rates. This suggests that a coding screen, similar in concept to the screens CMS applied in the past to device-dependent APCs is necessary to ensure more appropriate and accurate payment rates for brachytherapy APCs. In the past, CMS has used only correctly coded claims to determine brachytherapy payment rates and we recommend that they do so for 2006.

The analysis properly removed the costs of the brachytherapy source ("C" code) line items before calculating the total packaged costs of APC. This should be clear, as the

median costs for all claims are quite close to the median as published by CMS. The higher costs of the correctly-coded claims is not due to the improper inclusion of the source costs in the median calculation, but reflects the impact of selecting claims from hospitals who carefully and fully code the charge data.

Correctly coded claims are defined as an outpatient claim that contains a brachytherapy procedure code and at least one brachytherapy source device "C" code as indicated below.

Correctly Coded Brachytherapy Claims

APC	CPT Codes	Brachytherapy Device "C" Codes
312 Radioelement Applications	77761, 77762, 77763, 77776, or 77777	C1716, C1718, C1719, C1720, C2616, C2632, or C2633
313 Brachytherapy	77781, 77782, 77783, 77784, or 77779	C1717
651 Complex Interstitial Radiation Source Application	77778	C1716, C1718, C1719, C1720, C2616, C2632, or C2633

We recommend that CMS use only correctly coded claims for brachytherapy APCs 312, 313, and 651 to determine the final 2006 HOPPS payment rates by selecting claims that accurately reflect the procedure, source and device coding and revise the final payment rate for 2006 to reflect the appropriate cost of the brachytherapy procedure(s).

New Technology APCs

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

Mentor Corporation is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization that is not subject to procedural protections that are required for public policy. AMA meetings are closed to the public and the basis for decisions are not available to the public, including hospitals and physicians. The AMA CPT Editorial Panel has no voting representatives from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

Clearly, the requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions. This requirement may be an unlawful delegation of federal decision making to a private organization.

Category I codes are typically assigned to a procedure that has become an accepted standard of care thus defeating the purpose of adoption of new technology. If manufacturers are forced to apply for a CPT code before sufficient information is

available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code that often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries, and many commercial payers.

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives of manufacturers on the decision making panel, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiary's full access to high quality care in the hospital outpatient setting just as other patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me.

Sincerely,

Clarke Scherff
Vice President
Regulatory Compliance and Quality Assurance
Mentor Corporation

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Cyberonics

PPS / D-D
Grassley / Dorgan

Hagel
McCain
Kane
Snowe
Hart
Bayh

September 16, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

To Whom It May Concern:

Cyberonics Inc. (sole manufacturer of the VNS Therapy System), would like to take this opportunity to comment on the Proposed Rule for hospital outpatient department reimbursement, as published by the Centers for Medicare & Medicaid Services (CMS) in the July 25, 2005 *Federal Register.* We appreciate the considerable effort CMS has put into the development of the Outpatient Prospective Payment System (OPPS). However, there are still several issues that warrant comment. Specifically, we will address items discussed in **Section IV *"Proposed Payment Changes for Devices, Device-Dependent APC's***."

Cyberonics does not receive reimbursement directly from CMS, but the proposed changes to the OPPS have an impact on the nature of our business. The proposed decrease to ambulatory payment classification (APC) 0039 is of great concern. More than 70% of all VNS Therapy patients elect neurostimulator replacement upon battery depletion also known as end of service (EOS). It is concerning that the proposed rate for APC 0039, the only APC that is billed in a VNS Therapy System EOS replacement procedure, would not allow a hospital to recoup their costs for the procedure and the device.

See **Addendum A** for a complete description of Cyberonics, mission, approved indications, history of Medicare's NCD for epilepsy and depression related facts. In addition, see **Addendum B** for detailed analyses of the data and more complete comments on the problems and issues with the proposed rate and rate setting methodology.

Proposed 2006 payment for APC 0039 -

As shown in Table 1, the 2006 proposed rates for ambulatory payment classification (APC) 0039, Level I Implantation of Neurostimulator would reimburse hospitals approximately 15% percent less than in 2005.

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Table 1
2006 Proposed Payment for APC 0039 vs. 2005 Actual Payment Rate

Procedure	CPT Code	APC	APC Payment 2005	APC Payment 2006 Proposed	2005 v. 2006 Change	2005 v. 2006 % Change Adjusted
Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling	61885	0039	$12,532	$10,717	- $1,815	- .1448%

Implant Procedure and Device Acquisition Costs -

On average it costs hospitals $3,000 to perform the VNS Therapy System neurostimulator replacement procedure (excluding device costs). Hospital acquisition cost for the Model 102 NCP System in 2004 was $11,999.

The data clearly demonstrate device acquisition and procedure costs, $15,000 in total have been undervalued in APC 0039 for EOS replacement procedures as proposed. The payment amount proposed, $10,717 is lower than hospital device acquisition cost and without consideration for implantation procedure costs.

Data Issues -

The data included in the claims database for APC 0039 present many of the same concerns as in years past. VNS Therapy System claims were not captured or they were eliminated from the rate setting analysis as in the past due to the single v. multiple claims criteria applied by CMS in their analysis. The majority of VNS Therapy System implants are a simultaneous implant of the neurostimulator and lead, thus creating a claim that is lost to the "multi" claim file instead of being captured as a "single" claim. In addition, for EOS replacement procedures, if the hospital codes a secondary procedure for any particular reason that claim would also be lost to the "multi" claim file.

A thorough analysis of the claims which grouped to APC 0039 and were included in the proposed rate further explains why the proposed rate would not cover a hospital's cost for VNS Therapy implant (device and procedure). Factors contributing to an insufficient rate include:

- a decision by CMS not to use correctly coded claims (i.e. eliminating multi-procedure claims),
- refusal by CMS to acknowledge that charge compression exists,
- the lack of C codes,
- the decision to deny use of external data and
- the ongoing failure of hospitals to correctly code and bill for services provided

In addition to the above mentioned structural problems with rate setting methodology, perhaps the biggest factor contributing to the undervaluing of APC 0039 is an analysis of the procedures

within APC 0039 grouped by diagnosis. This analysis clearly shows that the claims used for rate setting purposes where a diagnosis of epilepsy was present (the only claims associated with VNS Therapy System implants) were significantly under represented. Epilepsy related claims accounted for only 69 of the 805 claims or .085% of the procedures.

Median cost for the epilepsy related claims are among the highest in the group. Utilizing the CMS cost methodology, epilepsy claims have a median total cost 22% above all other claims. Not surprisingly, the 736 claims with lower overall medians are driving down the weights and rates.

Recommendations:

Appropriate payment to hospitals will ensure that Medicare beneficiaries continue to have access to medical technologies like the VNS Therapy System in the outpatient hospital department. Our recommendations are outlined below:

- **Stabilizing Rates** – In terms of VNS Therapy System reimbursement, CMS made good progress with the 2005 rates and we would urge CMS to consider options that would maintain payment rates at no less than 100% of the 2005 rates plus the annual update factors applied to all APC's.

  Since CY 2002 there has been a -31% decrease to APC 0039. The proposed payment rate for APC 0039 would be the third decrease in a four year period. Changes that result in a decrease in year over year payment rates create financial issues for hospitals, especially in an environment where costs are rising.

- **Utilization of external data to validate rates and/or justify changes to be incorporated into the APC's medians** - Cyberonics recommends that CMS make adjustments, as it has in previous years for APC 0039 that more accurately represent acquisition cost of the device and procedure-related services, including the incorporation of external data provided by manufacturers and other stakeholders into the median cost calculations.

Sincerely,

Mario Vanini, MHA, CPC
Director, Health Policy & Reimbursement

Addendum A

Cyberonics manufactures and sells an implantable neurostimulator used to deliver Vagus Nerve Stimulation (VNS) Therapy. Cyberonics mission is:

> "To improve the lives of people touched by epilepsy, depression and other chronic disorders that may prove to be treatable with our patented therapy, VNS."

Currently, the approved indications for our product (VNS Therapy System) are as follows:

> **Epilepsy** - "As an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures that are refractory to antiepileptic medications."
>
> **Depression** - "As an adjunctive long-term treatment for chronic or recurrent depression for patients 18 years of age and older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments."

History and Medicare's National Coverage Decision on VNS Therapy:

On July 16, 1997 the United States Food and Drug Administration (FDA) approved Vagus Nerve Stimulation (VNS) Therapy as an adjunctive treatment for patients with medically refractory partial onset seizures.

VNS Therapy represented the first new approach to the treatment of epilepsy in nearly 100 years and payers moved quickly to assess the evidence supporting VNS Therapy and issue favorable coverage and payment policies to ensure access to those who needed this therapy.

- CMS (formerly HCFA) National Coverage Policy issued April 1999.
- National Blue Cross and Blue Shield Technology Evaluation Center reviewed at February 10, 1998 meeting: The NCP System meets all coverage criteria.
- CHAMPUS/TRICARE.
- Kaiser, United, Aetna and virtually all payers cover and reimburse VNS Therapy.

In the eight years since FDA approval, patients living with medically refractory epilepsy have gained almost universal access to VNS Therapy. The value of VNS Therapy to improve the lives of people with poorly controlled epilepsy is now overwhelmingly supported with a very large peer reviewed literature with over 100,000 patient years of experience worldwide. The rationale for CMS's National Coverage Decision and the favorable coverage decisions made by the vast majority of private payers and State Medicaid organizations was and remains as follows:

- Epilepsy is a Chronic and Expensive Disorder,
- VNS Provides Long Term Seizure Control and Quality of Life and

- Long Term Seizure Control and Quality of Life Results in Reduced Healthcare Utilization and Savings for Payers.

On July 15, 2005, the FDA approved VNS Therapy for treatment resistant depression (TRD). Americans with TRD for the first time have an informatively-labeled, long-term treatment option.

- Major Depressive Disorder (MDD) is one of the most prevalent and serious illnesses in the US, affecting nearly 19 million Americans over the age of 18 in any given year.

- MDD is associated with increased mortality due to suicide and co-morbid general medical conditions including heart disease and stroke.

- Depressed patients use twice the healthcare services as non-depressed patients. Total annual costs of depression in the U.S. exceed $80 billion including $30 billion in annual direct treatment costs.

- Studies show that annual healthcare costs for patients with TRD exceed $40,000 per patient per year, approximately six times the cost of those without TRD.

- Peer reviewed publications of VNS Therapy studies in TRD have demonstrated that adding VNS Therapy to a patient's treatment regimen increases response and remission rates 2 to 4 times over the long term.

We are actively working with public and private payers to provide the peer review evidence supporting the use of VNS Therapy for TRD in developing favorable coverage much like in epilepsy.

Addendum B

We will provide detailed comments on topics raised by the proposed rule below:

Section IV *"Proposed Payment Changes for Devices, Device-Dependent APCs*."

- Proposed 2006 Payment Rate for VNS Therapy
- "C" codes for implantable devices
- Data and Methodology
- Cost to Charge Ratio
- Wage Index
- Recommendations

Implant Procedure and Device Acquisition Costs -

More than 70% of all VNS Therapy patients elect neurostimulator replacement upon battery depletion also known as end of service (EOS). It is concerning that the proposed rate for APC 0039 by itself, the only APC that is billed in an EOS replacement procedure, would not allow a hospital to recoup their costs for the procedure and the device. On average it costs hospitals a few thousand dollars (includes OR staff, OR time, OR supplies, recovery, etc) to perform the VNS Therapy System neurostimulator replacement procedure (excluding device costs). Hospital acquisition cost for the Model 102 NCP System in 2004 was $11,999, total costs for the device and the procedure would be ~$15,000.

Proposed 2006 Payment Rate for VNS Therapy:

As shown in Table 1, the 2006 proposed rates for ambulatory payment classification (APC) 0039, Level I Implantation of Neurostimulator and APC 0225, Level I Implantation of Neurostimulator Electrodes would reimburse hospitals approximately the same in total as 2005. Thus, continuing to provide access to those Medicare beneficiaries in need of VNS Therapy as an initial implant.

However, the proposed decrease to APC 0039 is our greatest concern. As you can see, device acquisition and procedure costs have been undervalued in APC 0039 for EOS replacement procedures as proposed. The relative weight for APC 0039 would not get a hospital back to cost. The amount reflected is lower than hospital acquisition cost and without consideration for implantation procedure costs.

Table 1
2006 Proposed Payment for APC's 0039 and 0225 Vs. 2005 Actual Payment Rates

Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling	**61885**	**0039**	**$12,532**	**$10,717**	**- $1,815**	**- .1448%**
Incision and implantation of neurostimulator electrodes; cranial nerve	64573	0225	$ 11,996	$13,865	$1,869	.1347%

The year-to-year fluctuation in the individual APC rates cause concern. Stabilization of rates is what hospitals need to be able to provide consistent access to "device dependent APC's" One way to avoid that possibility would be to maintain the current 2005 medians.

Consistent with previous year's comments and this year's rate setting data and methodology, we have great concern going forward. The inclusion of external data and other such considerations in the past has created reimbursement rates for APC's like APC 0039 and APC 0225, which allow Medicare beneficiaries access to technologies like VNS Therapy. However, as we will discuss later in the data section, hospitals have not established correct coding and billing for devices, and there are no disincentives in the system for incorrect coding and billing.

There are two statements prior to table 15 of the NPRM for device-dependent APC's that are very worrisome.

> "Thus, for CY 2006 OPPS, we calculated median costs for these APC's using all single bills without regard to whether there was a device code on the claim" and, "We expect that this would be the last year in which we would make an across the board adjustment to the median costs for these device-dependent APC's based on comparisons to the prior year's payment medians."

Using bad data and planning to make no more exceptions for what is known to be bad data are factors that are bound to limit access to technology.

The proposed unadjusted 2006 OPPS APC median under the above-suggested circumstances for APC 0039 is -23%. This puts hospitals in a troublesome situation for APC 0039. Alternatively, an adjusted median of no more than a -15% reduction on device dependent APC's like APC 0039, albeit better, is not modest, and will force hospitals to decide whether to furnish those services or not. Under either methodology alone, our concern is that a Medicare beneficiary might not get a neurostimulator replacement when needed based on the proposed reimbursement rate.

We urge CMS to consider the previous OPPS changes made in 2005 in order to remain consistent with the original intent of the statute. Since device codes were not required in 2003 and optional in 2004 we see no difference. CMS even stated that "relatively few hospitals chose to code for devices."

"C" Codes for Implantable Devices:

Optional "C" Codes: Proposing to base CY 2006 OPPS device-dependent APC medians on CY 2004 claims data is concerning. Given the fluctuation in the claims data, and changes in CMS's methodologies, it is impossible to set accurate payment rates based on claims that were accepted with or without a device. Below you can see a year by year C code requirement for APC 0039;

CY 2000 - pass thru on specific device C codes (C1048),
CY 2001 – pass thru on Category C codes (C1048 becomes C1767),
CY 2002 – pass thru on C1767,
CY 2003 – C codes not required,
CY 2004 – C codes optional and
CY 2005 – C codes required but only enforced on specific APC's.

Hospitals have had no incentive before CY 2005 to correctly code claims with C codes. By requiring that all "C" codes be billed, and returning claims without them, or providing some other incentive to improve coding, we believe that hospitals will be more vigilant in reporting the total costs of providing device-related services.

Data and Methodology:

- Data
  - VNS Therapy claims not represented
    - # hospitals coding for epilepsy captured declines
    - # epilepsy patients captured declines
  - Inadequate/missing charges

- Methodology
  - Charge Compression/Cost-to-charge-ratio
  - Wage Index.

The Moran Company (TMC) provided Cyberonics a thorough analysis of the 2004 Medicare Public Use File (1/1/04 – 12/31/04). After reviewing the claims data and CMS's methodology, it became clear why the payment rate calculated for APC 0039 as proposed in the July 25, 2005 rule is inadequate for hospitals performing VNS Therapy neurostimulator EOS replacement procedures. Below we address our specific concerns with elements of the Proposed OPPS rule as related to APC 0039.

Data -

TMC created a data set that was highly comparable to the data published by CMS in the proposed rule. See table 2 below, which shows minimal variation between the two for claims that fit the "Single" evaluation criteria.

Table 2 (APC 0039)

	CMS Data	TMC replication of CMS	Percent Variance
Claims	809	805	0%
Median Cost	$9,905	$9,797	1%

Summary of Data Issues -

The data included in the claims database for APC 0039 present several concerns. Again, as noted in the 2004 file, VNS Therapy claims were not captured or they were eliminated from the rate setting analysis as in the past due to the single v. multiple claims exclusion rule created by CMS. The majority of VNS Therapy System implants are a simultaneous implant of the neurostimulator and lead, thus creating a claim that is lost to the "multi" claim file instead of being captured as a "single" claim. In addition, for EOS replacement procedures, if the hospital codes a secondary procedure for any particular reason that claim would also be lost to the "multi" claim file.

There were 194 hospitals that submitted claims, which grouped to the APC 0039 single file. Further analysis of those claims explains why the proposed rate for APC 0039 would not cover a hospital's cost for VNS Therapy implant (device and procedure). Some of the single claims contained no device charge, 194 hospitals submitted a total of 552 claims with no appropriate device charge (i.e. C1767) or supply charge. On average, charges and costs for procedures and devices are lower than expected. The average procedure charge was $4,369 while the average device charge was $28,308. When you apply the Cost-to-Charge Ratio (CCR) the average procedure cost becomes $1,468 and the average device cost becomes $9,511. Well below the hospital's actual costs for a VNS Therapy neurostimulator implant.

We further broke down the procedures within APC 0039 by diagnosis to better understand what types of procedures were represented. Specifically, CPT code 61885 (insertion or replacement of cranial neurostimulator pulse generator or receiver, single electrode array) should be accompanied by an epilepsy diagnosis if it were for a VNS Therapy implant. TMC pulled 805 single claims for APC 0039. As you can see in Table 3 below, epilepsy related claims accounted for only .085% of the procedures in that group. *Similar to the numbers we have reported in previous years, we know based on implant cards collected that Medicare beneficiaries accounted for approximately 1,061 or 18% of our total implants in CY 2004. Of those 1,061 Medicare cases, roughly 222 or 21% were EOS replacement procedure cases.* Supporting the fact that VNS Therapy implants are severely underrepresented in the rate setting data.

Utilizing the CMS median cost methodology, the median cost for the single epilepsy related claims was $13,024 v. $9,797 for all other claims in APC 0039, showing the median cost for those services are the highest in the group. Further comparisons of the diagnosis splits show claims with Parkinson's had median cost of $11,630 and the other (i.e. not epilepsy or Parkinson's) had a median cost of $8,590. If you used epilepsy and Parkinson's combined, median total cost were $11,773. Looking back at CY 2003 splits, $12,118, $11,605 and $10,847 were the median costs for diagnosis codes 345, 780 and 332 respectively. Showing

that these claims have consistently been the higher cost claims in the APC. Keep in mind that APC 0039 has only one CPT code (61885) mapping to it. A correctly coded claim for insertion of a cranial neurostimulator should only be represented by epilepsy or Parkinson's related diagnoses.

Utilizing the CMS cost methodology, single bill epilepsy claims have median total costs 22% above all other claims. Not surprisingly, the 736 claims with lower overall medians are driving down the weights and rates.

There continues to be widely varying resources currently grouped to APC 0039 that cause these inequities. VNS Therapy product function, acquisition cost, cost per year of therapy and cost effectiveness are much different than other products included in APC 0039.

Table 3

Diag.	Description	Claims	Percent	Median Cost
332	Parkinson's	302	38%	$11,619
V53	Fitting and adjustment	194	24%	$ 8,439
333	Other extrapyrmidal disorder	130	16%	$ 9,236
996	Complication peculiar to proc.	91	11%	$ 7,160
345	**Epilepsy**	**39**	**5%**	**$13,095**
780	**General Symptoms**	**30**	**4%**	**$12,730**
781	Symptoms involving nervous	8	1%	$ 8,677
340	Multiple sclerosis	3	0%	$31,503
343	Infantile cerebral palsy	2	0%	$ 1,779
322	Meningitis	1	0%	$ 5,084
378	disorder of binocular eye movement	1	0%	$14,722
438	Late effects of cerebrovasc	1	0%	$21,660
707	Chronic Ulcer of skin	1	0%	$13,128
723	Other disorders of cervical region	1	0%	$20,694
724	Other & unspecified disorders of back	1	0%	$ 2,884

Further analysis of the 69 single claims submitted by 55 hospitals was done. Only 13 hospitals have sufficient charges on the procedure line and 2 hospitals have sufficient charges on the supply/device lines to cover the acquisition costs of the device and no facility submitted adequate charges on both the procedure and the device/supply lines. Assuming the current cost of the VNS Therapy System neurostimulator is $11,999 and conservatively $3,000 for implantation procedure costs, none of the 55 hospitals submit charges that generate sufficient costs for the procedure and device as proposed in the CY 2006 rule. 55 hospitals submitted 41 (60%) of the 69 claims with no device C code, while 5 other claims had no supply code. Meaning, nearly 70% of the claims were without a supply or C code.

The above concerns combined with the methodology used to calculate weights and payments leave the VNS Therapy neurostimulator underrepresented/undervalued in APC 0039. Without data that is representative of the VNS Therapy System it is not possible to properly reflect costs of VNS Therapy.

Cost-to-charge Ratio:

Charges for higher cost technologies have been reduced too much under CMS's current methodology of applying department-specific or hospital-specific cost-to-charge ratios to amounts on claims demonstrating "charge compression." The 2004 charge data for higher-cost technologies like the VNS Therapy System show that hospitals are still not marking up these technologies at a rate adequate to recapture their costs once the cost-to-charge ratio is applied. As a result, CMS's current application of cost-to-charge ratios creates an underestimation of the hospital's costs, undermining the base APC rate.

Current device acquisition costs to the Hospital for neurostimulator implant procedures are approximately $12,000 before any overhead costs for implantation, but the median costs for these items after the cost-to-charge ratio adjustment of claims are calculated to be well below acquisition cost.

Wage Index:

CMS's application of wage index on the device portion of the APC will continue to further undervalue technologies. For the 55 hospitals making single epilepsy claims, no hospital's wage adjusted payment exceeds $15,000; a level that would cover the device and the procedure for the hospital. Four hospitals wage adjusted payment would cover the device but not the procedure, and 51 hospitals will receive a wage adjusted payment for APC 0039 that is less than the $12,000 acquisition cost of a VNS Therapy neurostimulator.

Summary:

Cyberonics believes that CMS must continue to consider additional data and alternative methodological approaches. We urge CMS to conduct in-depth analyses of the claims, review additional information, consider alternative methodologies, and recalculate APC's like 0039 to assure that more complete and accurate hospital costs are captured and reimbursed.

Recommendations:

We hope that CMS will incorporate the recommendations below for CY 2006 rate setting and into the future. Appropriate payment to the hospitals will ensure that Medicare beneficiaries continue to have access to medical technologies like the VNS Therapy System in the outpatient hospital department. Our recommendations are outlined below:

- **Stabilizing Rates** – In terms of VNS Therapy System reimbursement, CMS made good progress with the 2005 rates and we would urge CMS to consider options that would maintain payment rates at no less than 100% of the 2005 rates plus the annual update factors applied to all APC's.

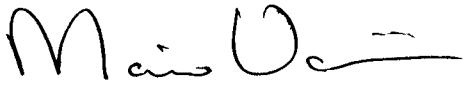
Since CY 2002 there has been a -31% decrease to APC 0039. The proposed payment rate for APC 0039 would be the third decrease in a four year period. Changes that result in a decrease in year over year payment rates create financial issues for hospitals, especially in an environment where costs are rising.

- **Utilization of external data to validate rates and/or justify changes to be incorporated into the APC's medians** - Cyberonics recommends that CMS make adjustments, as it has in previous years for APC 0039 that more accurately represent acquisition cost of the device and procedure-related services, including the incorporation of external data provided by manufacturers and other stakeholders into the median cost calculations.

- **Eliminate Wage Index on Claims where more than 80% is Device Related** -Exempt the device portion of the APC rate for specific devices from the wage index or net payment will continue to result in access problems for Medicare beneficiaries. When the cost of devices exceeds a specific threshold or a percentage of the APC rate, CMS should specify the portion of the APC attributable to the devices, and should exempt this portion from the wage index, since device costs are not generally subject to local wage variations.

The steps taken in developing the 2005 rates, including the use of manufacturers' and other outside data sources for specific device-related APCs, especially APC 0039, were important improvements that should be incorporated into the ongoing methodology for developing APC rates. We appreciate the opportunity to provide comments on the Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2006. We also look forward to working with CMS to resolve our concerns.

Sincerely,



Mario Vanini, MHA, CPC
Director, Health Policy & Reimbursement

InSightec
Bringing therapy into focus

Imaging
NT APCs

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Burley
Hunter
Spolter
Hostetler
Kane
Sanow
Hart
Borell

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on CMS-1501-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Dr. McClellan:

InSightec is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding the hospital outpatient prospective payment system (OPPS) proposed rule for 2006 (Proposed Rule). Our comments address the proposed Ambulatory Payment Classification (APC) for magnetic resonance (MR) guided focused ultrasound (MRgFUS), as we are the manufacturer of the ExAblate 2000 System used to perform this service. Currently, there are two Current Procedural Terminology (CPT) codes used to bill for MRgFUS[1], both of which are assigned to APC 0193 and are proposed to be assigned to that APC again in 2006. The current and proposed APC assignment was done without the benefit of claims data on either code. As explained in more detail below, the resources utilized by hospitals in providing each service far exceed those used for any of the other procedures in APC 193. Indeed, if 2004 claims data were available for these codes, it is almost certain that inclusion of 0071T and 0072T in APC 0193 would present a violation of the two times rule. As a result, the payment rate established for APC 193 is insufficient for the simple or complex MRgFUS service and hospitals will be unable to perform either service, depriving patients of access to this important new technology in the treatment of uterine fibroids. For these reasons and consistent with the recommendation of the APC Advisory Panel, **InSightec requests that CMS remove these codes from APC 193 and assign them to separate new technology APCs, specifically 0071T to APC 1529 and 0072T to APC 1534.**[2]

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[1] These two codes are **CPT 0071T** (Focused Ultrasound ablation of uterine leiomyomata, including MR guidance, total leiomyomata volume less that 200 cc of tissue) and **CPT 0072T** (Focused ultrasound ablation of uterine leiomyomata, including MR guidance, total leiomyomata volume greater than or equal to 200 cc of tissue).

[2] The Proposed Rule does not address MRgFUS specifically in the preamble such that it is not clear what caption should be referred to for this comment. We believe that this issue most appropriately falls under "New Technology APCs" since there are no data upon which to determine a median cost and a relative weight for each code.

Background

The ExAblate 2000 System uses a technology known as *focused ultrasound* to non-invasively deliver high levels of energy into the body to treat uterine fibroids with heat. It is indicated for the treatment of uterine fibroids in pre-menopausal women. This is similar to ultrasound commonly used in diagnostic imaging, but is much higher power. When focused to a small point, it is capable of generating high levels of heat in a small volume. The technique is non-invasive. It is performed in conjunction with a magnetic resonance imaging (MRI) system, which provides a "window into the body" to enable the physician to "see" where he/she is treating and to monitor the thermal effects of the treatment.

The patient lies on her stomach inside the MRI system. Sophisticated planning software is used together with the MRI system to acquire anatomic images, identify the target tissue to be treated and draw the treatment plan. During treatment, a small beam of focused ultrasound is directed at the target for ~15 seconds and heats the tissue. MR images taken during each heating cycle provide an image of the target tissue and the degree of heating. The system then moves to the next treatment point and the process is repeated about once every 90 seconds until the entire volume has been treated. Typically, 30-60 individual pulses are delivered over a 3 hour period to complete a simple treatment and 45-80 individual pulses delivered over a four hour period to complete a complex treatment. The patient requires light sedation for the procedure and is conscious, providing feedback to the physician. After the treatment, she will remain in the hospital for 1-2 hours and then can be taken home. Most patients resume normal activities in the home or at work within 1-2 days.

Effective July 1, 2004, the American Medical Association (AMA) created two new codes for the technology (0071T and 0072T).[3] In the final rule setting the 2005 OPPS payment rates, CMS assigned these codes to APC 0193, with a payment rate of $758.17. 69 Fed. Reg. 65682, 65890 (Nov. 15, 2005). According to the Proposed Rule, these codes again would be assigned to APC 193 and the proposed rate is $865.48. 70 Fed. Reg. 50680, 50686 (Aug. 26, 2005).

This proposed classification of 0071T and 0072T was discussed at the APC Advisory Panel (Panel) meeting on August 18, 2005. At the end of the discussion of this issue, the Panel unanimously recommended that these codes be removed from APC 193 and assigned to a new technology APC. Although the Panel made no recommendation as to the exact new technology APC into which the codes should be assigned, it recommended that CMS consider information from stakeholders to ascertain which new technology APC would be appropriate.[4]

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[3] For your convenience, the description of these codes with a clinical vignette from the AMA's CPT Changes 2005 book is attached.

[4] The Panel's recommendations are available at http://www.cms.hhs.gov/faca/apc/panel-recommendations.pdf.

Discussion

InSightec is in agreement with the APC Advisory Panel – 0071T and 0072T should not be assigned to APC 193 in 2006. Such an assignment would result in a payment rate that would not even approach the costs incurred by hospitals in performing either procedure and will prevent hospitals from being able to perform either service. In the spirit of the second recommendation by the Panel, InSightec has worked with two hospitals to develop information to help CMS determine the correct new technology APC for assignment.[5] The information obtained in these efforts support our recommendation to assign 0071T to APC 1529 and 0072T to APC 1534.

A. CPT Codes 0071T and 0072T Should Be Assigned to New Technology APCs

A fundamental tenet of OPPS is that items and services must be assigned to APCs in which there is both clinical and resource coherence.[6] Typically, this is accomplished based on a review of adequate hospital claims data. MRgFUS is a new technology and does not have sufficient levels of claims data that support CMS' assignment of these new procedure codes to APC 193. In setting the 2006 OPPS rates, hospital outpatient claims from calendar year 2004 will be used to calculate and set the relative weights. During that year, *no hospital claims data were generated for these codes*, as they were not implemented until July 1, 2004 and CMS did not establish them as payable OPPS codes until January 1, 2005. Moreover, the technology was approved by the Food and Drug Administration in October 2004. Therefore, it is clear that CMS does not have sufficient claims data to support the assignment of these CPT codes to APC 193.

When the resources involved in providing MRgFUS are more fully understood, there is no doubt that APC 193 is an inappropriate assignment for these codes. This is evident from looking at the cost proformas (Attachment A) from two leading hospital providers. These proformas demonstrate **per procedure cost** for simple cases that is as much as five times the median cost of the highest median cost of other procedures in APC 193 ($1304.68 for CPT code 57010). Likewise, the proformas show that the **per procedure cost** for complex cases is as much at six times the median cost of the procedure with the highest median cost in APC 193. These figures are well in excess of the factor of 2 that generates a "two times" rule violation. Because the resources involved in the MRgFUS procedures differ so significantly from the resources involved in the procedures in APC 193, these codes must be removed from APC 193. Since the agency puts "a service within a new technology APC group until we acquire adequate data to assign it to a clinically appropriate APC group"[7] and there are no claims data for 0071T and 0072T, the appropriate solution is to assign the codes into new technology APCs.

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[5] Given that the technology is new and has not diffused widely at this point and the short timeframe for action, InSightec has focused its efforts on two institutions. We note also that the Medicare population receiving the service is likely to be small (yet not nonexistent) because it is indicated for pre-menopausal women.

[6] *See* 70 Fed. Reg. at 42709 (discussing moving two codes into APC 163 "since they are similar clinically and use similar hospital resources").

[7] 70 Fed. Reg. at 42677.

B. CMS Should Assign 0071T to APC 1529 and 0072T to APC 1534

Having demonstrated that continued assignment into APC 193 is inappropriate under OPPS rules on APC assignment, the question is into which APCs should the codes be assigned. With no OPPS claims data to assist in that determination, InSightec approached two hospitals that use MRgFUS to help CMS understand the resources involved. Attached is a document that contains a breakdown of the actual costs incurred by two hospitals (Hospital A and Hospital B) in furnishing the simple and the complex MRgFUS procedure. The proformas demonstrate a variance in costs reported between the individual institutions for both 0071T and 0072T. Hospital A reported an average cost of $4,072 per case for 0071T and an average cost of $5,849 for CPT Code 0072T. Hospital B reported an average cost per case of $5,873 for CPT code 0071T and $8,200 for CPT Code 0072T.[8] The proformas also indicate a difference in resources between the simple and complex procedures. This difference is the result of the added time that it takes for the complex procedure. It is also important to note, as reflected in the 2005 CPT Changes book description of 0071T and 0072T, that the magnetic resonance procedures are included in these codes and thus are not billed separately. Of course, that impacts the resources expended by hospitals when they perform the service billed under 0071T or 0072T.

Given this cost information, InSightec reviewed the existing APCs to ascertain whether any such APCs would be an appropriate grouping for assignment of either CPT code. While various APCs would satisfy CMS' desire for resource coherence, there would not seem to be clinical coherence in including 0071T or 0072T in any of them. As a result, and given that there are no 2004 claims data available, InSightec believes, as the APC Panel does, that the appropriate mechanism to address these codes is a new technology APC. Based on the results of the submitted cost proformas, InSightec recommends that simple MRgFUS procedures (billed under 0071T) be assigned to New Technology APC 1529 ($5,500-$6,000), and that complex MRgFUS procedures (billed under 0072T) be assigned to APC 1534 ($8,000-$8,500).

InSightec recognizes that there are discrepancies in the cost information provided by the two hospitals. Since this is a new technology that is only beginning to diffuse, we believe it is important that, in setting the rates for the codes, CMS ensure that all hospitals can afford to provide the services. If assignment is based on either the lowest cost submitted, or blended or average cost, the APC assignments will result in a payment rate below the cost to Hospital A of providing MRgFUS and thus could deny patients suffering with uterine fibroids from access an important advance in the treatment of that condition.

Conclusion

Again, InSightec appreciates the opportunity to comment on the Proposed Rule. For the reasons discussed above, InSightec respectfully urges CMS to:

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[8] The cost variance between the two hospitals can be attributed to differences in institutions specific costs reported for system depreciation/maintenance and salaries/benefits expense.

1. Remove CPT codes 0071T and 0072T from APC 193; and
2. Assign the codes to appropriate new technology APC – APC 1529 for 0071T and APC1534 for 0072T.

Consistent with the recommendations of the APC Advisory Panel, we hope that CMS will move these codes out of APC 193 and into new technology APCs so that OPPS rates will no longer serve as such a harsh disincentive to utilizing this technology. Please do not hesitate to contact me at 214-630-2000 with any questions concerning this comment.

Sincerely,

Robert W. Newman
Vice President and North America Pole Manager

Attachment: CPT Procedure Description

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An Insider's View

AMA press

2005

detection of S3, S4 heart sounds in the identification of cardiac conditions associated with left ventricular dysfunction. Acoustic heart sound recording is achieved through acoustic sensors. Parenthetical notes were added to each add-on code to instruct the users to report the add-on code in conjunction with the listed primary procedure.

Clinical Example (0068T)

A previously asymptomatic 56-year-old Caucasian female with the major cardiac risk factor of a 40 pack-year smoking history presents to the emergency department complaining of shortness of breath that began approximately an hour before arrival. The skin of the patient is prepped and the combined electrocardiogram (ECG) and phonocardiographic electrodes are properly placed on the patient's chest as are the electrocardiographic electrodes. Correlated audioelectric cardiographic signals are then obtained and computer analysis performed. The results are then reviewed by the physician, interpreted, and a report generated.

Description of Procedure (0068T)

Service includes prepping the skin, applying the electrodes in their customary ECG positions, determining the proper positioning of the dual sensors in the V3 and V4 positions, reviewing the raw recording to verify proper placement and appropriateness of signals, acquisition of the signals, reviewing the computer analysis (sound and ECG), and generating a report.

●**0071T** Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue

●**0072T** total leiomyomata volume greater or equal to 200 cc of tissue

►(Do not report 0071T, 0072T in conjunction with 51702 or 76394)◄

Rationale

Codes 0071T and 0072T were established to describe new technology for magnetic resonance-guided focused ultrasound (MRgFUS) ablation. MRgFUS is the first non-invasive thermal ablation device that produces coagulative necrosis of soft tissue at a precise focal point within a soft tissue target in the body. It is also the only ablation system that is fully integrated with a magnetic resonance (MR) imaging system that provides continuous guidance and monitoring. It provides accurate volumetric therapy planning through the utilization of system specific therapy planning software, which computes the time and number of sonifications required for therapeutic efficacy. It has the ability to provide on-line thermometric imaging that provides "real time" feedback and treatment verification. MR images taken during the sonification provide a diagnostic image of the target tissue and a quantitative "real time" temperature map overlay to confirm the therapeutic effect of the ablation treatment. MRgFUS is a safe and effective noninvasive alternative to hysterectomy, myomectomy, and uterine fibroid embolization in the treatment of uterine fibroids.

Code 0071T should be reported when the total leiomyomata volume is less than 200 cc of tissue and code 0072T should be reported if it's greater or equal to 200 cc of tissue.

Total leiomyomata should be documented in the medical record when this procedure is performed.

A parenthetical note with exclusionary codes has been added and a corresponding cross-reference in the Radiology subsection has been added following code 76394 directing users to the new codes.

Description of Procedure (0071T)
The patient is evaluated by the treating physician for the procedure, and specifically for administration of intra-venous conscious sedation (IVCS). A repeat focused history and physical exam is performed to rule out any interval pertinent changes since the last office visit and as IVCS is still deemed appropriate by the physician, additional informed consent for the sedation is obtained.

At that time then a nurse inspects the skin surface, if necessary further pre-operative preparation is performed, and an IV and a Foley catheter in the urinary bladder are placed.

On completion of all the preparatory steps, the patient enters the magnetic resonance imaging (MRI) suite, is placed on the treatment table, and a 3-plane localizer scan is completed to confirm that the patient is positioned correctly on the table to allow a complete treatment. If necessary, the patient is re-positioned and a second series is run. Multi-planar T2W images are then obtained of the entire pelvis, spine and skin anteriorly.

The treating physician and team review all MR images, (the original ones and the new current ones). The skin contact is evaluated and then the target fibroid (s) is identified and the selected volume is outlined by the operating physician in the treatment software program. Computer analysis of the MR images is performed by the treating physician to calculate the safety of the treatment routes and dose delivery mechanism through the tumor(s) to be treated.

3D renderings are created within the computer by the treating physician, and dose simulations are reviewed.

The treatment plan and all beam path simulations in three dimensional (3D) are then reviewed by the operating physician prior to proceeding with therapy. The beam path (before and after the target) is evaluated carefully to ensure safe passage of the thermal therapy. If necessary adjustments can be made to the position of the patient, or the transducer in the table. The transducer is tilted or rolled as necessary to ensure optimal angulation of the beam. The spine and posterior pelvis are carefully evaluated as the beam should avoid the sacral nerve plexus.

Conscious sedation is administered and vital signs monitored by a nurse under the direct supervision of the operating physician throughout the procedure. The nurse remains in the room with the patient at all times. Prior to the first sonication the patient is instructed to communicate all sensations to the treating physician during or after each sonication. The patient is given an emergency shut off button to hold and she can terminate the procedure at any time. The nurse and treating physician can also do this. The patient remains awake and in regular communication with the treating physician through out the entire procedure.

DAPA®

family recovery programs

90

PHP

Asplen
Kane
Snow
Hart
Bazell

September 14, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

RE: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1501-P

DAPA® Family Recovery Programs is a freestanding Community Mental Health Center in Houston, Texas. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1501-P and a 15% rate reduction for CY2006 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A $40/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas. A daily per diem of $241.57 cannot be justified with these expenses.

2. CMS identified the Median cost of group therapy at $82.31. Our program offers four (4) services per day at a minimum. This summarizes to a median cost of $429.24. A per diem of $241.57 cannot be justified with these expenses.

6260 westpark, ste. 150 • houston, texas 77057 • phone:713.783.8889 • fax: 713.783.9486 • int'l: 1.800.828.3272

3. Many of our patients are Medi-Medi's. Medicaid cuts are strongly threatened here in Houston, Texas. If the 20% copay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to $193.26 ($241.57 x .80). A daily per diem of $241.57 cannot be justified with this situation.

4. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

5. Based on the above issues, DAPA® Family Recovery Programs asks that CMS leave the per diem unchanged from the CY2005 rate of $281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our three PHP programs have had a combined total of eight-hundred and sixty-seven (867) admissions so far in CY2006, and every one would be a high risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Greg Kuras, JD
Administrator

GK:jkb

Blues Management, Inc.
6260 Westpark, Suite 250
Houston, Texas 77057

Telephone: 713-783-8889

Telecopier: 713-783-0499

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PHP

Alspen
KAHC
Samad
Healthcare

September 14, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Re: Partial Hospitalization Response to Proposed Changes to the Hospital Outpatient PPS-CMS-1501-p

On behalf of the Association of Ambulatory Behavioral Healthcare (AABH), we sincerely appreciate the opportunity to submit comments regarding CMS's proposed OPPS rates concerning Partial Hospitalization Services under APC 0033.

AABH represents over 350 providers of partial hospitalization and other ambulatory behavioral health services across the country. Our members consist of hospitals, community mental health centers (CMHCs), individual providers, and volunteers dedicated to cost effective patient treatment within the ambulatory continuum. Since 1975, AABH has worked cooperatively with state and federal agencies, professional groups, payers and others to provide research and training, and to better define and support the understanding of ambulatory approaches to behavioral healthcare. Our members subscribe to a code of ethics requiring the highest standards for professional and programmatic conduct, and share a common belief that individuals with acute mental illness have a better chance of recovery and healthy functioning if treated in the same communities where they work, attend school, and maintain family relationships. Based on our long-standing work in this area, we wish to work in partnership with CMS to ensure preservation and proper recognition of Medicare's partial hospitalization benefit.

AABH is deeply concerned about the grave impact a rate reduction of 14% could have on partial hospitalization and hospital outpatient services. We believe this type of cut could severely jeopardize the very existence of the partial hospitalization benefit itself.

The Association of Ambulatory Behavioral Healthcare respectfully comments as follows:

1. **CMS data does not support a PHP per diem rate of $241.57.**

During the identification of the proposed rate (before the correction notice) in CMS-1501-p, CMS referenced the CY 2005 combined hospital-based and CMHC median per diem costs of $289.00. As providers in the medical industry, we are well aware that the industry inflation rate is approximately 3.5% which creates an approximate cost of $299.12 per day for the coming year. As providers, we are very conscious that salaries, benefits, insurance, supplies, utilities, etc. have not gone down. These figures strongly conflict with a per diem rate of $241.57.

In addition, CMS has identified the true Median Cost of HCPCS 90853 for group therapy at $82.31. With a minimum of 4 services per day (many programs offer more), CMS would recognize the minimum cost at $329.24 per day. These data are inconsistent with a rate of $241.57 and indicate that a higher payment rate is necessary to prevent PHP from running substantial deficits that will risk financial viability.

2. **Medicaid cuts substantially impact copays.**

At the proposed CMS rate of $241.57, the Medicare payment is actually 80% or $193.26 with the copay of $48.31. Not all, but most Medicare recipients eligible for this benefit are also Medicaid recipients for their copay.

Many states (example-West Virginia) have recognized partial services as a Medicaid benefit. Unfortunately, their reimbursement rates are generally one-third to one-half of the Medicare rate at best. These states have declared that when crossover claims are submitted for the copay, that if the provider has already received payment above the state rate, then they do not pay any of the copay. This in essence creates a per diem rate of $193.26 for CY 2006, further below the unacceptable rate of $241.57.

3. **CMS' s calculations for the CY 2006 PHP per diem payment is diluted.**

CMS states that per diem costs were computed by summarizing the line item costs on each bill and dividing by the number of days on the bills. This calculation can severely dilute the rate and penalize providers. All programs are strongly encouraged by the fiscal intermediaries to submit all PHP service days on claims, even when the patient receives less than 3 services. Programs must report these days to be able to meet the 57% attendance threshold and avoid potential delays in the claim payment. Yet, programs are only paid their per diem when 3 or more qualified services are presented for a day of service. If only 1 or 2 services are assigned a cost and the day is divided into the aggregate data, the cost per day is significantly compromised and diluted. Even days that are paid but only have 3 services dilute the cost factors on the calculations. With difficult challenges of treating the severe and persistently mentally ill adults, these circumstances occur frequently.

4. **The proposed PHP per diem rate also compromises Hospital Outpatient Services.**

CMS pays hospital facilities for Outpatient Services on a per unit basis **up to** the per diem PHP payment. As previously shown, CMS has identified Group Therapy HCPCS code 90853 with a true Median Cost of $82.31. Most patients involved in the Outpatient Services are participating 1-3 days and generally receive 4 or more services on those days. While programs provide 4 services the per diem limit will only allow them to be "paid their cost" for 3 services (3 x $82.31= $246.93) The fourth service again is "on the house".

5. **Cost Report Data frequently does not reflect Bad Debt expense for the entire year.**

As the cost report data is proposed surrounding Bad Debt, many "recent" bad debt copays of the last 4-5 months of the fiscal year have not completed the facility's full collection efforts and therefore are not eligible for consideration of bad debt on the cost report. Those that are, can only be recovered up to 55%. These costs are not being considered in the CMS data and severely short change the rate calculations.

6. **Data for settled Cost Reports fail to include costs reversed on appeal.**

CMS historically has reduced certain providers' cost for purposes of deriving the APC rate based on its observation that "costs for settled cost reports were considerably lower than costs from 'as submitted' cost reports." (68 Federal Register 48012) While CMS's observation is true, it fails to include in the provider's costs, those costs denied/removed from "as submitted" cost reports, and subsequently reversed on appeal to the Provider Reimbursement Review Board ("PRRB"), subsequently settled pursuant to the PRRB's mediation program, or otherwise settled among the provider and intermediary. During the relevant years at issue, providers of PHP incurred particularly significant cost report denials, but also experienced favorable outcomes on appeal. Because the CMS analysis did not take into consideration what were ultimately the allowable costs, its data are skewed artificially low. The cost data used to derive the APC rate should be revised to account for these costs subsequently allowed.

Based on the above issues, AABH would recommend that CMS take the following course of action:

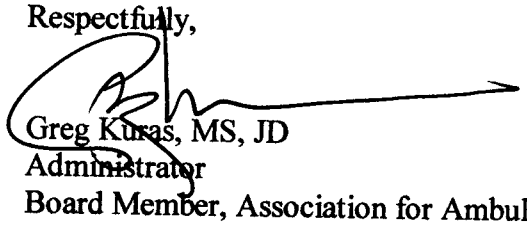
1. Allow the PHP per diem to remain the same as the 2005 per diem rate of $281.33 while CMS continues to examine the data and research the numerous problems identified.

2. Consider a methodology that uses an average over time. Blending a three or four year average cost and/or rate would help eliminate a drastic cut of the per diem such as the 14% proposed cut for CY 2006.

3. Allow energy, time and resources to develop a reasonable payment methodology by working with organizations such as AABH. AABH would welcome the opportunity to study and research data with CMS to develop a payment rate that is fair, consistent and predictable.

Thank you, for the opportunity to respond to this critical issue.

Respectfully,



Greg Kuras, MS, JD
Administrator
Board Member, Association for Ambulatory Behavioral Healthcare

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GE Healthcare

101 Carnegie Center
Princeton, New Jersey 08540
USA

September 14, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed 2006 HOPPS Rule – CMS-1501-P

Dear Dr. McClellan:

GE Healthcare is a unit of General Electric Company that is headquartered in the United Kingdom with expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, disease research, drug discovery and biopharmaceuticals. Worldwide, GE Healthcare employs more than 42,000 people committed to service healthcare professionals and their patients in more than 100 countries.

We appreciate the opportunity to submit these comments on the proposed hospital outpatient prospective payment system (HOPPS) rule published in the July 25, 2005 Federal Register

Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals -"Non Pass-Throughs"

I. $50 Threshold for Separate Payment of Drugs

The threshold for establishing separate ambulatory payment classifications (APCs), set at $50 pursuant to statute, will expire at the end of 2006. CMS has specifically requested comments on the use of alternative thresholds for packaging drugs and radiopharmaceuticals in 2007.

We recommend that CMS continue the $50 threshold for separate payment of drugs, particularly in light of the changing methodology for payment of drugs. As we note below, simultaneous changes in methodology, code descriptors and handling codes may precipitate sharp declines in payment, thereby potentially jeopardizing patient access to the drugs.

II. Separate Payment for Low Osmolar Contrast Material (LOCM)

We applaud CMS' proposal to pay for contrast agents under the HOPPS using the ASP-based methodology as is the case in the physician office and freestanding facilities. The activation of the Q codes for these products will facilitate consistent reporting and payment across settings of care as well as promote more consistent coding of the products and thereby generate more accurate claims data for future analyses.

We recommend that CMS activate the Q codes for MR contrast (Q9952 and 9954) as well in order to maintain consistency for these drugs across settings.

III. Payment for Radiopharmaceuticals in 2006

Cost to Charge Ratio (CCR) - CMS proposes a temporary one year policy to pay for radiopharmaceuticals in 2006 based on a hospital's CCR or charges adjusted to cost. CMS' intent is to maintain consistency whenever possible between the payment rates for radiopharmaceuticals from CY 2005 to CY 2006. CMS expressed concern in using the congressionally mandated General Accountability Office (GAO) survey and study since the GAO-reported purchase prices were substantially lower than 2005 payment levels and CMS does not want rapid reductions in payment to adversely affect beneficiary access to services utilizing radiopharmaceuticals.

CMS also cites the MedPAC study as another rationale for using CCR. The study indicated that hospitals currently include the charge for pharmacy overhead costs in their charge for the radiopharmaceutical. CMS believes that payment based on charges converted to cost would be the best available proxy for the average acquisition cost, along with the handling cost.

Recommendations for use of CCR

1. Appropriate cost to charge ratio

Hospital charges, notwithstanding the MedPAC report, do not uniformly include handling and overhead costs. Moreover, department-specific CCRs will fail to convert charges to "average acquisition costs" and could result in significantly lower payment than 2005 levels. Thus, there is a risk that use of some cost to charge approaches will cause rapid and severe payment reductions and fail to approximate average acquisition costs.

We recommend that CMS (or fiscal intermediaries) use a hospital's general CCR rather than a department-specific CCR. The former is more reflective of a hospital's overall charges. As stated previously, hospitals' pharmacy charges do not always reflect

radiopharmaceutical handling costs and therefore the CCR may not fairly represent the acquisition cost of such a drug. MedPAC has cited radiopharmaceutical handling costs as complicated and costly. Thus, the typical hospital departmental CCR in the range of .10-.30 would seriously fail to reflect hospital radiopharmaceutical charges. Hospitals' general CCR, typically in the rage of 0.4 to .05, when applied to radiopharmaceuticals would be a better proxy and reflect the MedPAC findings on overhead costs.

2. Creation of G codes for radiopharmaceutical handling costs

The MedPAC report identified 7 categories of drugs, with distinct handling costs. Radiopharmaceuticals had the highest relative median costs of all drugs. CMS has proposed to create three drug handling cost C codes. None of these three C codes would apply to radiopharmaceuticals. The absence or exclusion of radiopharmaceuticals from these C codes creates a major risk that the drugs will be improperly paid, especially since radiopharmaceuticals have the highest handling costs.

We support the recommendation of the Council on Radionuclides and Radiopharmaceuticals (CORAR) for the creation of 5 additional G codes unique to radiopharmaceuticals:

GRPX1	Diagnostic radiopharmaceutical (not compounded by hospital) requiring special handling, protective shielding and monitoring;
GRPX2	Therapeutic radiopharmaceutical (not compounded by hospital) requiring special handling, protective shielding and monitoring;
GRPX3	Diagnostic radiopharmaceutical (compounded and requiring calculations performed correctly and then compounded correctly by hospital) requiring special handling, protective shielding and monitoring; and
GRPX4	Therapeutic radiopharmaceutical (compounded and requiring calculations performed correctly and then compounded correctly by hospital) requiring special handling, protective shielding and monitoring
GRPX5	Radiopharmaceutical handling costs for separately billed compounding fees for external radiopharmacies

We also support CORAR's recommendation that all radiopharmaceuticals be paid separately to facilitate appropriate recognition of handling costs for all radiopharmaceuticals.

3. Payment for Radiopharmaceutical Handling Costs

CMS should pay hospitals, utilizing the above G codes, for the handling and overhead costs that are necessary for the safe and effective administration and disposal of radioactive isotopes and radiopharmaceuticals. These payments should be in addition to payment based on a CCR-determined amount.

IV. Average Sale Price (ASP) Reporting in 2006 and Payment for Radiopharmaceuticals in 2007

CMS proposes to require radiopharmaceutical manufacturers to begin reporting ASP in 2006. In 2007, CMS proposes to determine payment in the hospital outpatient setting for radiopharmaceuticals based on ASP. As CMS so eloquently stated in the proposed rule, it is extremely difficult to determine an accurate ASP due to the unique features and handling of the drugs. The manufacturers sell components or kits to radiopharmacies or hospitals, and thus, manufacturers do not have access to prices for the end product/unit dose, as is the case for conventional drugs. There is no standard or uniform ASP for the end product, typically a unit dose recognized by a HCPCS code

Our concern is that a new payment methodology for radiopharmaceuticals based on ASP poses legal, policy, and practical challenges that may be insurmountable given the short period of time for implementation. Moreover, in 2006, providers will be challenged with changes in code descriptors, payment methodology and handling codes. Alternate payment methods, such as CCR with refinements, must be considered. Our reasons are as follows:

1. Legal barriers to use of ASP

The Medicare Modernization Act (MMA) authorized CMS to continue Medicare Part B payment methodologies including, for example, the use of invoice based payment. See section 303(h). CMS has explicitly recognized this provision by exempting radiopharmaceuticals from reporting ASP. CMS is now proposing to reverse this statutory standard and agency recognition. We suggest that there were compelling reasons that Congress required continuation of payment methodologies for radiopharmaceuticals under Part B and that CMS cannot, by regulation, reverse this statutory authority.

2. Policy and Practical Barriers to use of ASP

Radiopharmaceuticals are typically formed from two components. These components may be considered in essence "raw materials". For example, different manufacturers produce and sell technetium generators. The pricing of the technetium generator will vary from manufacturer to another. The technetium must be combined with another component such as tetrofosmin to form the end and finished product – a unit patient dose. Thus, one manufacturer does not know if a hospital, using a combination of components to generate the end product patient dose, uses exclusively that manufacturer's raw materials or a combination of another manufacturer's raw materials. More important, the manufacturer has no way to calculate the average sales price of the end product patient dose, since the manufacturer only knows the price of its own component.

Furthermore, those components may be combined to generate a vial from which multiple doses can be drawn. The manufacturer does not know how many doses will be drawn from a vial. Pricing for a unit dose would thus vary depending on how many doses are drawn from a vial.

These unique distribution, formulation, and pricing features make it essentially impossible for a radiopharmaceutical manufacturer to calculate an ASP for radiopharmaceuticals. The manufacturer could report an ASP for a component but it would be different from the price of the end product. Because CMS requires the manufacturer to certify that the ASP report is accurate, radiopharmaceutical manufacturers could not in good faith sign such certifications. GE Healthcare strongly objects to any new regulatory requirements that impose liability that is not within the manufacturer's control.

V. Summary

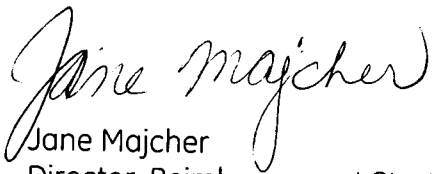
We recommend that CMS

- Continue the $50 threshold for separate payment of drugs
- Activate the MR contrast codes (Q9952 and 9954) for consistency with LOCM
- Use a hospital-specific cost to charge ratio to pay for radiopharmaceuticals AND adopt G codes to denote handling costs associated with these drugs
- Forego the proposal to collect ASP data from manufacturers for radiopharmaceuticals. Instead, utilize hospital cost to charge ratio data to set payment

GE Healthcare recognizes the challenge that CMS faces in revising payment methodologies. We would be pleased to meet with CMS to expound upon our recommendations in greater detail.

Thank you for the opportunity to comment on this important rule. Should you have any questions, please do not hesitate to contact me at 609-514-6701 or at jane.majcher@ge.com.

Sincerely,



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FAX: [703] 519.3865

NATIONAL RURAL HEALTH ASSOCIATION

September 15, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1501–P
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, CMS–1501–P, 70 Fed. Reg. 42,674 et seq. (July 25, 2005).

Dear Administrator McClellan:

The National Rural Health Association (NRHA) appreciates the opportunity to comment on the rule regarding proposed changes to the hospital outpatient prospective payment system ("OPPS") and calendar year 2006 payment rates, and specifically the Expiring Hold Harmless Provision for Transitional Corridor Payments for Certain Rural Hospitals and Rural Hospital Adjustment, both of which are discussed beginning on page 42,698. We appreciate your ongoing commitment to rural health care, and the NRHA looks forward to working with you in our mutual goals of improving access and quality of health care for all rural Americans.

The NRHA is a national nonprofit membership organization that provides leadership on rural health issues. The association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through advocacy, communications, education and research. The NRHA membership of more than 10,000 is made up of a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health.

NRHA requests that CMS continue hold-harmless protections for rural SCHs.

A. Expiring Hold Harmless Provision for Transitional Corridor Payments for Certain Rural Hospitals

NRHA urges CMS to reconsider its decision to terminate the hold-harmless provision for transitional corridor payments, at least with respect to SCHs. NRHA recognizes that Congress established this protection for a limited period, and that the statutory authorization for this protection is set to expire at the end of this calendar year.

Nonetheless, the need for this protection remains, and CMS has ample statutory authority to perpetuate it.

The sole community hospital program was created to maintain access to needed health services for Medicare beneficiaries in isolated communities. The SCH program ensures the viability of hospitals that are geographically isolated and thus play a critical role in providing access to care.

Because SCHs are the sole source of hospital services in their community, Congress has long appreciated the special role of SCHs and the need to afford SCHs special recognition and protections under the Medicare program to ensure their continued viability. For example, SCHs are specially treated under Medicare's inpatient prospective payment system ("IPPS"). Whereas most hospitals are reimbursed under the IPPS rates, SCHs are paid the greater of the IPPS rates or a cost-based payment.

In setting SCHs apart, Congress recognized that these hospitals provide critically necessary services to Medicare beneficiaries in areas where access to other providers is limited or unavailable, and expressed a desire to buttress these hospitals with special payment status to ensure their viability.

For the same reasons that Congress extended special treatment to these hospitals in the context of the IPPS, Congress extended special treatment to SCHs under the OPPS. Specifically, section 411 of the Medicare Modernization Act provided that SCHs would be held harmless under the OPPS by paying SCHs under either the OPPS rate or a cost-based reimbursement formula, whichever is greater for the individual hospital.

Regrettably, cost considerations led Congress to limit the duration of this protection, and the congressional mandate that CMS provide this protection is set to expire. Nonetheless, the need for this protection remains. An examination of available CMS data indicates that approximately 339 of the 540 SCHs qualify for hold-harmless payments, and that the average hold-harmless payment adjustment is 21.04 percent above the OPPS payment the hospital would otherwise receive. While some SCHs will benefit by CMS's proposed 6.6 percent OPPS adjustment, this amount will not begin to compensate most SCHs for the hold-harmless protections that they will lose if CMS allows this protection to lapse.

Moreover, while helpful, the proposed 6.6 percent adjustment is not addressing the specific and unique needs of SCHs. Congress provided similar hold-harmless protection under the IPPS, because it recognized that SCHs should not operate with extensive Medicare reimbursement deficits.

The across-the-board payment adjustment simply does not assist hospitals that operate with extensive Medicare reimbursement deficits. Rather, it attempts to put rural SCHs on a level playing field with urban hospitals with respect to Medicare payments. While this may be a laudable goal, it does nothing to ensure the viability of SCHs, and to ensure access to hospital services in isolated communities. By its nature, some SCHs that have

costs lower than OPPS payments will benefit by the across-the-board payment adjustment, while those that have costs that exceed payments will experience payment deficits. These deficits may compromise the services these hospitals are able to offer to their communities, and the very viability of these hospitals.

For these reasons, NRHA urges CMS to extend the hold-harmless protections for SCHs. NRHA believes that CMS has the statutory authority to do so notwithstanding the expiration date in section 411. Section 1833(t)(2)(E) gives the Secretary broad discretion to adjust payments to hospitals of any type to ensure equity. Specifically, section 1833(t)(2)(E) provides, "the Secretary shall establish...outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals" (emphasis added). This authority permits the Secretary to apply whatever adjustment he deems necessary, and to any class or category of provider he deems appropriate. Hold-harmless payments for SCHs would be an "adjustment" for a "class of hospitals", and therefore authorized by this grant of discretion.

B. Rural Hospital Adjustment

NRHA applauds CMS for the work that it did to study cost differentials between urban hospitals and rural SCHs, and for its proposal to adjust payments for rural SCHs. NRHA certainly encourages CMS to finalize this proposal. However, NRHA asks CMS to clarify whether it intends to make this adjustment available beyond 2006, and whether it intends to reestablish the adjustment amount on an annual basis.

The NRHA appreciates the opportunity to submit these comments on the proposed rule. Please do not hesitate to contact Alan Morgan, Chief Executive Officer at 703-519-7910 if you have any questions about these comments.

Sincerely,

Hilda R. Heady

Hilda Heady
President

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Burley
Kane
Jones
Holt
Bizell

JCBlair
MEMORIAL HOSPITAL

IMAG.

September 12, 2005

Center for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern,

We just received information concerning a proposal made by the CMS to reduce the payment rate for FDG PET/CT procedures, effective January 1, 2006 to $1,250.

We are very concerned that the proposed amount is inadequate to cover our hospital costs and will force us to discontinue offering this service.

We believe that it is vital for the CMS to reimburse hospital providers for FDG PET/CT procedures at a higher rate in 2006. This will ensure that Medicare patients continue to have access to this important medical advance.

Sincerely,

Jim Smith,
Director of Radiology
J.C. Blair Memorial Hospital

1225 WARM SPRINGS AVENUE, HUNTINGDON, PA 16652 • 814.643.2290 • FAX 814.643.8813 • www.jcblair.org

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SCOD/A/D

Wednesday, September 14, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
445–G Hubert H. Humphrey Building
200 Independence Avenue, Southwest
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates [CMS-1501-P] – Non Pass-Throughs

Dear Dr. McClellan:

Smith & Nephew is a global medical technology leader specializing in the development of advanced, cost-effective medical treatments. In particular, Smith & Nephew specializes in cutting-edge therapies for advanced wound management, endoscopy and orthopaedics.

Smith & Nephew is committed to the development of innovative and lifesaving medical technologies, and the company welcomes CMS' similar commitment to Medicare beneficiaries nationwide.

Smith & Nephew respectfully submits these comments to request correction of the erroneous product classification and reimbursement rate proposed for DERMAGRAFT® in the Hospital Outpatient Prospective Payment System [HOPPS]. DERMAGRAFT [C 9201/J 7342] is a human fibroblast-derived dermal substitute used to treat diabetic foot ulcers. The apparent problem rests in how CMS is calculating the reimbursement for bioengineered, living human tissue products. The proposed rule sets the reimbursement for bioengineered, living human tissue products at a rate reflecting the mean costs derived from 2004 hospital claims data rather than as a "specified covered outpatient drug" at a rate of ASP plus six percent. The result of this payment change is a significant and inappropriate decrease in reimbursement that could jeopardize access to this important advance in chronic wound therapy.

Medicare Beneficiaries, the Incidence of Diabetes and Diabetic Foot Ulcers

First, it is very important to understand the importance of this product in successfully treating diabetic foot ulcers and the significance for the Medicare population, both for clinical and economic reasons. According to the American Diabetes Association, 18.2 million Americans [6.3 percent of the population] suffer from diabetes. In 2002, direct and indirect expenditures attributable to diabetes were estimated at

$132 billion. Direct medical expenditures alone totaled $91.8 billion: $23.2 billion for diabetes care, $24.6 billion for chronic complications associated with diabetes, and $44.1 billion for excess prevalence of general medical conditions.[1]

Diabetic foot ulcers affect approximately 15 percent of all diabetics at some point during their lifetime.[2] The average diabetic foot ulcer episode can last several months and in some cases years. Lingering diabetic foot ulcers significantly increase medical expenditures. Costs of ulcer care have been estimated in the range of $4,595 per ulcer to nearly $28,000 for the two years after diagnosis.[3] The majority of diabetic foot ulcers are treated in the hospital outpatient setting, but severe ulcers can result in extended hospitalization. Research has found that the length of stay of diabetes patients listing a foot ulcer condition is 59 percent longer than for diabetes patients without ulcers.[4]

In addition, diabetic foot ulcers can often lead to more serious medical problems, including lower extremity amputations and increased mortality rates. The longer an ulcer persists, the greater the possibility that the patient will develop a serious infection that may lead to hospitalization and possible amputation. Diabetic lower-extremity ulcers are estimated to be responsible for 92,000 amputations every year.[5] The CDC reported in 2003 that approximately 60 percent of all lower extremity amputations occur among people that suffer from diabetes, and of those amputations, approximately 85 percent are preceded by a foot ulcer.[6] Within five years of a person's first lower extremity amputation, 28 – 51 percent of patients with diabetes require a second leg amputation[7], and the five-year survival rate after a lower extremity is 27 percent.[8] Total costs for diabetic foot disease in the United States, which include ulcer care and amputations, approach $6 billion annually.[9]

The cost of diabetic and other lower-extremity ulcers is particularly problematic for the Medicare program. In 2002, 20 percent of non-institutionalized Medicare beneficiaries were living with diabetes.[10] In 1995, over 400,000 Medicare beneficiaries, 7.3 percent of diabetic beneficiaries, had lower-extremity ulcers.

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[1] "Economic Costs of Diabetes," American Diabetes Association, *Diabetes Care* 26:917-932 [2003].
[2] Diabetes in America, 2nd Edition, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No 95-1468 [1995].
[3] "Incidence, Outcomes, and Cost of Foot Ulcers in Patients with Diabetes," Ramsey, S.D., et. al, *Diabetes Care* 22:382-387 [1999]; "Costs and Duration of Care for Lower Extremity Ulcers in Patients with Diabetes," Holzer, S.E.S. et. al, *Clin. Therapy.* 20:169-181 [1998].
[4] Diabetes in America, 2nd Edition, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No 95-1468 [1995].
[5] "A Cost Analysis of Diabetic Lower-Extremity Ulcers," Harrington, Catherine, et. al, *Diabetes Care* 23:1333-1337 [2000].
[6] "History of Foot Ulcer Among Persons With Diabetes, United States, 2000 to 2002," CDC,
[7] "A Cost Analysis of Diabetic Lower-Extremity Ulcers," Harrington, Catherine, et. al, *Diabetes Care* 23:1333-1337, [2000].
[8] "A Cost Analysis of Diabetic Lower-Extremity Ulcers," Harrington, Catherine, et. al, *Diabetes Care* 23:1333-1337, [2000].
[9] Diabetes in America, 2nd Edition, National Institute of Diabetes and Digestive and Kidney Diseases, NIH Publication No 95-1468 [1995].
[10] "Medicare Chart Book, Third Edition," The Henry J. Kaiser Family Foundation [2005].

A study released by the Lewin Group revealed that Medicare spent $1.45 billion in 1995 on lower extremity ulcer-related treatment. The study also found that Medicare expenditures per year for lower-extremity ulcer patients were $15,309 in 1995, compared to $5,226 for other Medicare patients – this is a 300 percent increase in Medicare cost from the average Medicare patient. In light of its findings, the Lewin report concluded that, "any wound care intervention that could prevent even a small percentage of wounds from progressing to the stage at which inpatient care is required may have a favorable cost affect on the Medicare system."

DERMAGRAFT® – Human Fibroblast-Derived Dermal Substitute

As noted above, DERMAGRAFT [C 9201/J 7342] is a human fibroblast-derived dermal substitute used to treat diabetic foot ulcers. The fibroblasts, seeded onto a bioabsorbable mesh material produce collagen, proteins, growth factors and cytokines – in essence, using active, living cells to replace damaged tissue in chronic ulcers. DERMAGRAFT is placed directly on the wound, and the fibroblasts are gradually absorbed to promote healing. DERMAGRAFT is FDA indicated for use in the treatment of full-thickness diabetic foot ulcers greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule, or bone exposure.

DERMAGRAFT has become an important treatment option for patients suffering from diabetic ulcers, as treatment with DERMAGRAFT results in faster wound healing and better patient outcomes. In clinical studies, patients treated with DERMAGRAFT were 1.7 times more likely to heal than the control group. In a recent study, patients experienced a 79 percent reduction in average time to 50 percent wound closure compared to the standard treatment group. After 12 weeks, 71 percent of ulcers healed when treated with DERMAGRAFT versus 14 percent of the control group. In another study, after week 12, the median percent wound closure was 91 percent among patients treated with DERMAGRAFT compared to 78 percent in the control group. Most importantly, there were virtually no reoccurring ulcers on healed DERMAGRAFT-treated ulcers after 42 months.

DERMAGRAFT Coding and Reimbursement

DERMAGRAFT was first reimbursed in the hospital outpatient setting with pass-through status as a device in 2000. In 2001, CMS changed the status of the product from a device to a biologic, stating that DERMAGRAFT was not eligible for pass-through status as a device because it was not surgically implanted or inserted into the patient. In 2001, Smith & Nephew submitted a biologic pass-through application. Since 2002, CMS has treated DERMAGRAFT as a biologic for reimbursement purposes:

Dates	Medicare Reimbursement Rate
April 1, 2002	DERMAGRAFT® acquired pass-through status as a biologic.
2002 - 2004	Reimbursed as a biologic at 95 percent AWP.
2004 to date	With passage of the Medicare Modernization Act [MMA], DERMAGRAFT was reimbursed as sole source biological in 2004 and 2005 under the "specified covered outpatient drug" provision.

Notably, the MMA defines a "specified covered outpatient drug" [SCOD] as a drug or biologic that [1] has a separate APC, and [2] is a biological for which payment was made on a pass-through basis on or before December 31, 2002. By this definition, DERMAGRAFT is clearly a "specified covered outpatient drug" under the statute because it [1] has a separate APC [9201], and [2] payment was made on a pass-through basis in April 2002, well before the December 31, 2002 deadline.

In the Notice of Proposed Rulemaking [NPRM] for the Hospital Outpatient Prospective Payment System rates for 2006, CMS proposes to reimburse DERMAGRAFT and other bioengineered, living human tissue products at a rate reflecting the mean costs derived from historical 2004 hospital claims data rather than as a "specified covered outpatient drug" at a rate of ASP plus six percent.

The result of this NPRM is a significant and inappropriate decrease in reimbursement. The proposed reimbursement rate under the NPRM is only $368.32 for 2006. This proposed reimbursement rate is well below the ASP reported quarterly to CMS for DERMAGRAFT. By way of reference, the most recent ASP for DERMAGRAFT reported to CMS was $548.66. Another bioengineered living tissue product, Apligraf [C 1305/J 7340], also faces a significant decrease, with a proposed reimbursement rate of $766.84 in 2006 as compared to $1,130.88 in 2005.

The result of this error is a significant decrease in Medicare reimbursement for DERMAGRAFT that will critically hinder patient access to this treatment. The new reimbursement rate is completely out of line with the product's current reimbursement rate and the actual cost of the product.

A study released by the Government Accountability Office on June 30, 2005, estimated DERMAGRAFT's average sales price [ASP] to be $545.10, based on its survey methodology. In 2004, DERMAGRAFT was reimbursed at a rate of $535.04, and in 2005, DERMAGRAFT is being reimbursed at a rate of $529.54. The proposed reimbursement rate under the NPRM is only $368.32 for 2006 – this represents a 30 percent decrease in reimbursement from 2005.

The proposed 2006 payment will not adequately reimburse providers for DERMAGRAFT, forcing providers to choose to rely on less effective, traditional therapies or use the more effective wound treatment at a significant financial loss. Providers will therefore limit use of the product, threatening the availability of this treatment option and possibly compromise the health of numerous Medicare beneficiaries.

The decrease in patient access to DERMAGRAFT® and other bioengineered, living human tissue products will have serious consequences for Medicare beneficiaries. Without access to DERMAGRAFT and other bioengineered, living human tissue products, Medicare patients that suffer from diabetic ulcers will have to rely on less effective conventional treatments and therapies. As noted above, conventional therapies often lead to longer healing times, increasing patient risk of infection and amputation. By creating disincentives to using more effective bioengineered, living human tissue products, Medicare is inadvertently increasing the likelihood of increased hospital stays, amputations, and other complications attributed to diabetic ulcers.

This drastic change in reimbursement rate will have a significant affect on patient access and product availability. It will make it extremely difficult for Smith & Nephew and other medical technology innovators to produce advanced technologies. Bioengineered, living human tissue products represent a crucial treatment option for patients suffering from chronic ulcers – Medicare should not implement a payment policy jeopardizing the availability of this important advanced wound-healing technology. As such, the proposed rule should be corrected to align with the agency's previous determinations that DERMAGRAFT is a "specified covered outpatient drug" and as such should be appropriately reimbursed at ASP plus six percent. On this latter point, Smith & Nephew strongly supports payment parity at levels set by ASP plus six percent for this product regardless of whether it is applied in the physician office setting or in the hospital outpatient setting.

Smith & Nephew appreciates this opportunity to submit comments to CMS regarding its 2006 Proposed Rule on the Hospital Outpatient Prospective Payment System. If you have any questions about these comments, please feel free to contact me at 202.626.8235.

Best regards,

Mary E. Hayter
Vice President, Government Affairs

ONCURA

Cryo

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Heygster
Kane
Snow
Hart
Bazell

September 13, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

VIA: HAND DELIVERY

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P

Dear Administrator McClellan:

These comments are submitted on behalf of ONCURA,[1] a leading manufacturer of state-of-the-art medical products and systems that employ novel hypothermic surgical technologies to destroy cancerous tissues. Our products include cryoablation systems, which offer highly effective and minimally invasive therapies for prostate and kidney cancer. Additionally we provide brachytherapy source products for the treatment of cancer.

We appreciate the opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services ("CMS") on July 25, 2005 *Federal Register* notice which proposes changes to the Hospital Outpatient Prospective Payment System (the "OPPS") for 2006. See Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, Vol. 70, No. 141 (July 25, 2005) (the "Proposed Rule"). The enclosed formal comments follow two meetings held with Herb Kuhn and CMS staff on July 22, 2005 (via conference call) and again on August 24, 2005 at the HHS Washington DC offices when the "Coalition to Preserve Prostate Cryosurgery" again met with Herb Kuhn and his staff.

We wish to comment on the following specific APC assignments related to cryotherapy:

APC 674 (CPT 55873) - *Cryoablation of the Prostate*

We set forth more detailed comments below.

* * *

[1] ONCURA was created in July 2003 by the merger of Amersham's brachytherapy business with Galil Medical Ltd's urology business.

ONCURA

I. APC 674 (CPT 55873) - CRYOABLATION OF THE PROSTATE

In summary, we believe **the proposed payment of $5659.13 for cryosurgical ablation of the prostate (CPT 55873, APC 674) does not accurately reflect the costs incurred by hospitals in administering this procedure**. Because this inadequate payment results from claims data that does not accurately capture the full charges related to this procedure on the UB-92 claims and cost information, **we urge the agency to revise the proposed payment using actual hospital acquisition cost data provided by manufacturers and the Moran analysis of the 2004 claims data**. We believe this is necessary in order to ensure continued access to this groundbreaking technology.

II. BACKGROUND ON CRYOSURGERY OF THE PROSTATE

A. Importance of Cryosurgery in Treatment of Prostate Cancer

In the United States, prostate cancer is the most common cancer seen in men and the second most common cause of male cancer deaths, and it is disproportionately more prevalent within the Medicare population. Cryotherapy systems are designed to treat prostate cancer by destroying cancerous tissue through the application of extreme cold temperatures delivered by cryoablation probes.[2] The number of probes used for a given procedure can range from 5 to as many as 20, depending on the particular case and the type of cryotherapy system used.

Recurrent and residual disease after initial therapy for prostate cancer is fairly common, with rates ranging from 25 percent to 85 percent depending on the initial therapy and disease type. Local recurrence of prostate cancer presents a difficult challenge, because there are limited therapeutic options: additional radiation rarely is an option due to the limits on cumulative doses, hormonal therapy is not curative, and salvage prostatectomy has limited efficacy.

Cryosurgery is highly effective in treating prostate cancer, and it is essentially one of the only treatment methods currently available for radiation-failure prostate cancer cases.[3] Moreover, patients are demanding initial treatment options for prostate cancer that are minimally invasive.

B. Effect of Innovations on Clinical Outcomes and Cost of Procedure

One of the most important technological advancements in this mode of treatment has been the development of smaller and more advanced probes, which enable the application of cryoablation with far more precision. Specifically, these increasingly sophisticated probes allow

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[2] These probes are inserted through the perineum into the prostate. Argon gas circulating through the probes generates very low temperatures causing the formation of ice, which destroys targeted cancer cells.

[3] The importance of cryosurgery in treating prostate cancer is evidenced by two separate national Medicare coverage decisions issued by CMS in 1999 and 2001. Cryosurgery is safe, effective, and medically necessary and appropriate in certain patient populations -- specifically, those patients with stages T1-T3 prostate cancer. It has demonstrated effectiveness through an absolute analysis and a comparative analysis. Its results are comparable to brachytherapy (involving implantation of a radioactive seed) and external beam radiation.

the physician to target cancerous tissue without causing damage to surrounding healthy tissue. This substantially reduces the likelihood of serious complications often consequent to prostate cancer therapy -- such as incontinence -- which avoids needless patient pain and suffering and reduces Medicare costs. In addition to decreasing complications, technological developments in cryotherapy systems have enabled this therapy to often be administered in hospital outpatient facilities, which produces savings for Medicare and allows patients to go home in less than 24 hours.

Prior to the expiration of the device pass-through payment for cryoablation probes (C2618) at the end of 2003, OPPS payment policy generally had responded appropriately to the migration of cryotherapy to the outpatient setting by establishing new-technology pass-through payments under the OPPS for cryoablation probes (C2618) and by setting adequate OPPS APC payment levels for the procedure. Unlike most devices, cryoablation probes continued on the pass-though payment list through 2003. We believe that we have been able to provide information in our meetings with CMS and these formal comments that will enable CMS to continue ensuring the availability of this therapy.

III. CURRENT 2005 OPPS PAYMENT FOR APC 674 AND PROPOSED 2006 OPPS PAYMENT FOR APC 674 IS BASED ON INACCURATE COST DATA

We are convinced that the current 2005 OPPS payment of $6392.68 for APC 674 is based on flawed claims data that understates the actual costs incurred by hospitals in administering this procedure. Our concerns are based on the number of hospitals which have discontinued their prostate cryotherapy programs and/or terminated their program due to lack of adequate reimbursement.[4] Based on the total number of facilities performing prostate cryosurgery, the number of hospitals who have discontinued their programs is alarming. While we appreciate CMS' efforts to consider external data in setting the current 2005 payment rates, even the blended rate of the median cost and external data continues to under reflect the actual cost of the procedure. Implementing the proposed 2006 payment rate of $5659.13 based on the median of $5780.04, listed on Table 15.--*Proposed Median Cost Adjustments for Device-Dependent APCs for CY 2006* of the Proposed Rule, results in a 12.00% decrease in the median and a significant decrease payment for APC 0674, Prostate cryoablation.[5]

We appreciate the efforts of CMS to recognize prostate cryoablation as a device dependant APC. As part of the "*Coalition to Preserve Cryosurgery*", Oncura contracted with *The Moran Company*[6] to perform an analysis of the 2004 Medicare Outpatient Prospective Payment System claims data file which was used to set the proposed payment weights for 2006.

CMS states in the latest NPRM that they chose not to require a device be coded on these claims because "APCs would be set based on very small numbers of claims" and that "the small subset of hospitals are unlikely to be representative of the resource costs of most

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[4] See Appendix A for list of hospitals that have discontinued prostate cryosurgery programs or will not allow the program due to inadequate reimbursement.

[5] See 70 Fed. Reg. at 42715.

[6] The Moran Company is an independent health care research and consulting firm.

hospitals that provided the service" [7] However, calculating median costs for APC 0674 using all single bills without regard to whether there was a device code on the claim results in an underestimate of the median costs because the cost of the cryosurgery probes was not included in a significant percentage of all single bills. This point is illustrated in the following excerpt from the Moran analysis:

- *The Impact of removing C2618 restriction was a median cost reduction of ~14%.*
- *Including this restriction would reduce the number of single claims to 45%, and reduce unique providers to 35% of total.*
- *Including the C2618 restriction, however, would not account for the providers reporting device charges under revenue codes.*
- *Including C2618 AND revenue codes (0270, 72, 78) with charges >$6,000—which would help differentiate device revenues from other general supplies—only reduces overall single claim count to 66% of total single claims and unique providers to 69% of total*
- *This approach alleviates the concern of how representative the resulting single claims and providers are when including only those claims that include the required devices.*
- *This approach ensures the cost of the packaged device is included in the median cost calculation for the procedure.*

When the C-Codes were no longer required on claims in 2004, many hospitals reported devices under the revenue codes and dropped the C-Code from the claim. The Moran analysis demonstrates several alternatives to utilizing a representative number of claims in order to establish the payment rate such that the 12% decrease is avoided[8]. Table 1 demonstrates the affect of using only those claims that contain the device C-code and a minimum charge of $6000. This results in a median of $7635. Additionally, a second alternative described in Table 1 utilizes only those claims that contain the device C-code and/or appropriate revenue codes and a minimum $6000 charge amount. This alternative would increase the number of claims for rate setting purposes and result in a median of $6892.

The $6000 charge threshold assumes a very conservative total device cost of $4000. We arrived at this threshold by assuming a mark up factor of 1.5 which assumes a CCR of 0.665. If we were to use the average CCR established by CMS of 0.420, the assumed markup factor would have increased to 2.38 and the threshold charge to $9500 based on the minimum $4000 cost of the device. Using the more conservative limiting charge of $6000 and the higher CCR and the minimal markup factor of 1.5 allows CMS to use a representative number of claims and results in a median of $7635.

[7] See 70 Fed. Reg. at 42713-14

[8] See Appendix B. Moran Analysis performed utilizing 2004 claims data set. Data was presented to Herb Kuhn and staff at August 24, 2005 meeting.

Table 1

SCENARIO	CLAIM CNT	PROVIDER COUNT	MEAN	MEDIAN	MIN	MAX	*% of total single claims*	*% of total unique providers*
C2618 with Charges >$6,000	432	71	$ 8,103	$ 7,635	$ 2,679	$ 23,411	*35%*	*30%*
C2618 OR Revenues (0270,0272,0278) with Charges >$6,000	822	161	$ 7,372	$ 6,892	$ 2,032	$ 23,492	*66%*	*69%*
C2618 regardless of charges	552	83	$ 7,326	$ 6,631	$ 2,191	$ 23,411	*45%*	*35%*
TMC Replication of CMS Methodology; No restrictions	1238	235	$ 6,367	$ 5,827	$ 1,056	$ 23,492		
CMS Published	*1248*	*N/A*	*$ 6,255*	*$ 5,780*	*$ 1,014*	*$ 23,415*		

**Percentages calculated from TMC replication of CMS methodology*
*** TMC replicated median within 1% of CMS published median*

Inaccurate Charge Reporting for Cryosurgery of the Prostate

While the claims data has improved since the inception of OPPS, we continue to believe that many hospitals have failed to submit claims to CMS for prostate cryosurgery that properly reflect the costs of supplies -- especially the cost of the cryoablation probes. As a result, we believe the proposed payment level will cause hospitals to incur substantial losses when administering this therapy. In the past, we have noted through analysis provided to the agency that hospitals frequently submit claims for this procedure that do not contain charges for probes in numbers sufficient to enable the procedure to be performed.

Some confusion as to the correct manner in which to report charges for cryosurgery of the prostate is not surprising, given the numerous changes over the past four years in the coding for this procedure[9]. Furthermore, because the majority of the "C" Codes expired at the end of 2002, our clients seemed confused regarding the fact that the C2618 would not expire until the end of 2003. Additionally, during this period, our hospital clients expressed particular difficulty with meeting the billing and coding requirements for cryoablation probes under the OPPS pass-through payment program -- including uncertainty as to how to reflect multiple units of a pass-through item during the course of a procedure. Many hospitals were also displeased that their actual pass-through payment was significantly less than their actual cost and felt that they needed to set their charges in a consistent manner and according to their cost accounting

[9] In 2000 G0160 New Technology APC 981 and G0161 APC 0268 no pass-through payment available; 2001 CPT 55873 New Technology APC980 and BIPA provision for pass-through payment (C2618) effective April 1, 2001; 2002 CPT 55873 New Technology APC 0982 pass through payment (C2618) with pro-rata reduction; 2003 CPT 55873 assigned to APC 674 and pass-through payment extended through 2003; 2004 and 2005 CPT 55873 assigned to APC 674 with cost of devices bundled into APC payment.

practices/policies. Manufacturers are not permitted to suggest how hospitals should establish their charges and so the educational efforts with the hospitals were difficult at times. Under such circumstances, it is not surprising that the claims data compiled from reported hospital charges do not provide an accurate picture of the total cost of performing cryosurgery of the prostate.

Anna Shields, President of Shields Products & Services, during the past 10 years, has consulted with and advised over 750 healthcare organizations nationwide.[10] According to Ms. Shields, there are several factors leading to healthcare facilities not capturing full charges on the claims. Therefore, claims data and cost reporting data to CMS is understated for services provided to patients. Ms. Shields indicated during the August 24, 2005 meeting with Herb Kuhn and CMS staff that of all the organizations that she has advised and consulted with nationwide, over 90% do not perform full-charge capture due to the following challenges[11]:

- Cash Flow Reimbursements
- Hospitals are judged externally on their financial viability from several benchmarks such as
  - Overall Accounts Receivable (AR) days
  - Adjustments to Gross Charges (Contractual Adjustments)
  - Reserve for Bad Debt (Patient self-pay portion after insurance payment)
- Challenges in implementing full-charge capture (and true patient cost accounting) are multifaceted, but the biggest by far is the immediate out of pocket cost to the organization to implement – including by not limited to:
  - Redesign of materials management
  - Redesign of clinical documentation
  - Charge master (CDM) redesign
  - Abstracting/Coding and Case Management redesign
  - Billing, Claims and AR Tracking Systems redesign

Additionally, there are very few if any immediate positive incentives to hospitals in implementing full-charge capture; there are also significant fears, financial investment costs, painful reveals and potential negative external perceptions of implementing full-charge capture[12]

Problem with Application of Cost-to-Charge Ratio to High-Cost Devices

As we have noted in the past, we believe CMS's methodology results in charge compression which contributes to inadequate payment rates for prostate cryosurgery. This is further validated in the summary report provided by Anna Shields.[13] As stated above, our hospital clients generally do not use a single formula to establish device charges, but rather typically use a sliding scale, whereby a lower markup is applied to relatively high-cost devices, such as cryoablation probes. When CMS applies a cost-to-charge ratio, however, it fails to take

[10] Ms. Shields has no affiliation with the cryosurgical manufacturers and is not a paid consultant for industry

[11] See Appendix C Report by Anna Shields

[12] See Appendix C Report by Anna Shields

[13] See Appendix C Claims data provided by hospitals to CMS reflects inconsistent markup and charging methodologies, in order to maintain "status quo" for gross charges to patients. Claims data is not truly reflective of full-charge capture, or accurate chart –to-charging methodology. Due to this, utilizing claims data and cost reporting data on which to base hospital reimbursement is understated in most cases, thus a reduction in reimbursement will significantly impact hospitals' ability to continue to offer this procedure to patients.

into account this sliding-scale approach to establishing device charges. Thus, applying the cost-to-charge ratio to the charges for cryoablation probes used for prostate cryosurgery produces an overstated markup for the device, and results in cost finding that understates the actual cost of the device to hospitals. This methodology harms high cost device dependant procedures.

Applying the CCR when hospitals do not use the CCR factor to establish their markup on items is illogical. We therefore suggest CMS take the most conservative approach in limiting the claims data set to claims with the appropriate device code (C2618) or the appropriate revenue codes (0270,0272, 0278) and a minimum $6000 charge threshold amount. In doing so, we believe that an adequate number of claims could be used for rate setting purposes.[14]

Inability to Report Charges for Supplies

An additional problem with charge reporting for prostate cryosurgery is the inability of hospitals to report charges for a number of supplies without specific codes used in connection with the procedure. There are several supply items that are required to perform prostate cryoablation and are unlikely to be used or stocked by the hospital for any other procedure. These supplies – such as urethral warming catheters, temperature sensor probes, and argon/helium gas (6,000 psi) -- are not insignificant costs to the hospitals. All are required in order to perform prostate cryosurgery. While the hospitals may have the ability to report such supplies under a supply revenue code, of the UB-92 claim forms that we have reviewed, we do not believe these supply costs are adequately reflected in the claims data. Again, the administrative burden to create and maintain supply charge master items that are not separately reimbursed or described by HCPCS codes results in many supply items being left off the UB-92 claim forms.

IV. RECOMMENDATION FOR APC 674 – PROSTATE CRYOABLATION

In light of the flaws in the cost findings for APC 674, we urge CMS to set the 2006 payment for APC 674 using an alternative to the OPPS claims-based methodology that ordinarily applies. As demonstrated in the Moran analysis of the claims data set, **CMS has the ability to use the claims data for prostate cryosurgery in such a manner that the medians would not decrease with a representative number of claims being used for rate setting purposes.** Basing payments on this defined claims data set would enable the agency to be confident that the payments for APC 674 reasonably relate more directly to the costs incurred by hospitals in performing cryoablation of the prostate. This relationship between payment and cost is critical to prevent Medicare OPPS payment policy from hindering the adoption of this emerging and groundbreaking therapy.

[14] As mentioned above, the $6000. charge threshold assumes a very conservative total device cost of $4000. times a conservative mark up factor of 1.5 which would assume a CCR of 0.665. If we were to use the average CCR established by CMS of 0.420, the assumed markup factor would have increased to 2.38 and the threshold charge to $9500. based on the minimum $4000. cost of the device. Using the more conservative limiting charge of $6000 and the higher CCR/minimal markup factor of 1.5, allows CMS to use a representative number of claims and results in a median of $7635.

ONCURA

VIII. CONCLUSION

ONCURA appreciates the opportunity to submit comments on the Proposed Rule, and we are eager to provide CMS with any information or clarification that would enable the agency to ensure Medicare beneficiaries continued access to cryosurgery of the prostate. We recognize that a system as complex as HOPPS will continue to encounter challenges for specific types of services, including cryotherapy. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me or you may also contact Lisa Hayden at (703) 948-7685.

Sincerely,

James McGlone
President/CEO Oncura

Oncura, Inc., 401 Plymouth Road, Suite 130, Plymouth Meeting, PA 19462
T 484 530 3900 F 484 530 3999
www.oncura.com

APPENDIX A

The following hospitals have closed or denied the start of prostate cryosurgery due to inadequate reimbursement:

1. HealthSouth Medical Center, Birmingham, AL
2. Baptist Golden Triangle in Columbus, MS
3. Maine Coast Memorial Hospital Ellsworth, ME
4. Good Samaritan Hospital Downers Grove, IL
5. JPS Health Network Ft. Worth, TX
6. George Washington University, Washington, DC
7. Long Island College Hospital - Brooklyn, N.Y
8. Physicians Hospital Portland, OR
9. McKenzie Willamette Hospital Springfield, OR
10. Blount Memorial Hospital Maryville, TN
11. University Medical Center Las Vegas, NV
12. Valley Hospital Las Vegas, NV
13. Desert Springs Medical Center Las Vegas, NV
14. JC Lincoln North Mountain Phoenix, AZ
15. St. Joseph Medical Center Phoenix, AZ
16. Twin Rivers Regional Medical Center Kennett, MO
17. Raulerson Hospital, Okeechobee, FL
18. Bluefield Medical Center, Bluefield, WV
19. Overlake Hospital Medical Center, Bellevue WA
20. Mt. Sinai Medical Center, Miami, FL
21. Parma Community Hospital, Cleveland, OH
22. Riverside Hospital, Riverside, CA
23. Fallbrook Hospital, Fallbrook, CA
24. Tucson Medical Center, Tuscon, AZ
25. Irvine Medical Center, Irvine, CA
26. Mercy Medical Center, Des Moines, IA
27. Our Lady of the Lake, Baton Rouge, LA
28. Opelousas General, Opelousas, LA
29. Summit Hospital, Baton Rouge, LA

APPENDIX B

Findings from an Analysis of CPT 55873 (APC 0674) in the 2004 HOPPS Claims

Prepared for Oncura and Endocare

Presented to CMS

August 24, 2005

THE MORAN COMPANY 1

Background

- APC 0674, "Prostate Cryoablation", consists of a single CPT code, 55873
- For CY 2005 rates, APC 0674 was considered "device dependent" and thus, HCPCS code C2618 was required to be on the claims used for rate setting.
  - Table 18 of Final Rule: FR/Vol. 69, No. 219/Monday, November 15, 2004/ Rules and Regulations.
- 2005 rates were based on 2003 claims data
- While C2618 was pass through in 2003, CMS deleted non-pass through device HCPCS in CY 2003

THE MORAN COMPANY 2

Background

- For 2006 rates, CMS proposes removing the C2618 restriction and ***would not*** require a device to be included on the claims used for rate setting.
- 2006 rates are based on 2004 claims data.
- C2618 was no longer pass through in 2004; however, CMS re-instated HCPCS coding of devices.
- TMC was engaged by Oncura and Endocare to evaluate the effect of this proposed policy.

* *FR/Vol. 68, No. 216/Friday, November 7, 2003/Rules and Regulations, pg. 63419*

THE MORAN COMPANY

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In 2004, we found

Restriction	Count of Single Claims	Mean Cost	Min Cost	Max Cost	Median	CV
55873 Alone	759	$ 6,823	$ 1,149	$29,333	$ 5,935	$ 58
55873 AND C2618	463	$ 7,484	$ 2,426	$23,014	$ 6,521	$ 45
% of total single claims	*61%*					

- that requiring C2618 to be present on a claim resulted in 61% of total single claims being used to calculate the median cost
- Using this methodology, the median cost for APC 0674 did not drop below 10% from the previous year.

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4

Rationale for Identifying Device Cost

- According to the manufacturers, a conservative estimate of the appropriate device charge associated with the cost of the "probes" used for prostate cryoablation is $6,000.

- Because of the changes to device coding in 2004 (C2618 was no longer pass through and CMS reinstated HCPCS coding for devices), we examined both C2618 and revenue codes (0270, 0272, or 0278) for the presences of device costs.

In 2005, we've examined claims for CPT 55873

- 64% of the original claims contained either HCPCS C2618 or a revenue center code with billed charges >$6,000.

- Of these claims, almost half used a revenue code (49%), slightly fewer used C2618 (46%), and 5% used both.

In 2005, we've examined claims for CPT 55873, continued

- 66% of the "pseudo" and "original" single claims contain the cost of the probes.
  - Almost half of these were billed using revenue center codes: 0270, 0272, or 0278.
- the remaining 34% of claims used in rate setting do not contain the cost of the device.

Rationale for Removing Device Restrictions

CMS states in the latest NPRM that they chose not to require a device be coded on these claims because "APCs would be set based on very small numbers of claims" and that "the small subset of hospitals are unlikely to be representative of the resource costs of most hospitals that provided the service"*

*FR/Vol.. 70, No. 141/Monday, July 25, 2005/Proposed Rule, pgs. 42713-14

Effect on Median Cost

- Removing the C2618 restriction reduces the median cost ~14%.

- Including this restriction would reduce the number of single claims to 45%, and reduce unique providers to 35% of total.

- Including C2618 restriction, however, would not account for the providers reporting device charges under revenue codes.

Effect on Median Cost, continued

- Including C2618 AND revenue codes (0270, 72, 78) with charges >$6,000—which would help differentiate device revenues from other general supplies—only reduces overall single claim count to 66% of total single claims and unique providers to 69% of total

- This approach alleviates the concern of how representative the resulting single claims and providers are when including only those claims that include the required devices.

- Ensures the cost of the packaged device is included in the median cost calculation for the procedure.

Effect on Median Cost, continued

SCENARIO	CLAIM CNT	PROVIDER COUNT	MEAN	MEDIAN	MIN	MAX	*% of total single claims*	*% of total unique providers*
C2618 with Charges >$6,000	432	71	$ 8,103	$ 7,635	$ 2,679	$ 23,411	*35%*	*30%*
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CMS Published	*1248*	*N/A*	*$ 6,255*	*$ 5,780*	*$ 1,014*	*$ 23,415*		

**Percentages calculated from TMC replication of CMS methodology*
*** TMC replicated median within 1% of CMS published median*

THE MORAN COMPANY

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SHIELDS
PRODUCTS & SERVICES

APPENDIX C

CMS Forum – Cryosurgery

08/24/05 10:00a-11:00a

Background on Presenter:

Anna L. Shields, PMP - President of Shields Products & Services, has been an IT professional for 20 years. During the past 10 years, she has consulted with and advised over 750 healthcare organizations nationwide (including acute, surgical, pediatric, psychiatric, and long term care facilities; sizes ranging from 12 bed to 600+ bed facilities; single and multiple entity healthcare organizations; private, public, government, educational and physician owned hospitals and healthcare clinics). In addition, she has consulted internationally with regional healthcare Directors of IT in Canada, responsible for 250 hospitals in three (3) provinces.

Her expertise, mission to improve healthcare delivery, approach to healthcare business culture and operational redesign; combined with her status as an independent consultant (consults with healthcare organizations directly - no affiliations or engagements with vendors or accounting/consulting firms), candid communication skills (honest, open, full-disclosure, real-world) and prior proven success as a project manager makes her a sought after industry expert adviser to healthcare executives - spanning over 100 hospitals nationally.

Shields mission to improve healthcare delivery is focused on three primary objectives:

1. Provide tools/education regarding integrated medical information systems technology - so that clinicians can continue to deliver quality patient care and improved patient outcomes
2. Assure that healthcare organizations can make a "margin" so they can achieve their "mission" – viable and sustainable financials that will allow them to continue to provide patient care services
3. Assure that current clinical and financial practices are compliant with federal and state regulations and guidelines; as well as preparing the organization to deal with constantly changing regulations and guidelines in healthcare

Ms. Shields has no affiliation with the cryosurgical manufacturers and is not a paid consultant for industry.

SHIELDS
PRODUCTS & SERVICES

CMS Forum – Cryosurgery

APPENDIX C

08/24/05 10:00a-11:00a

INTRODUCTION: Anna L. Shields, PMP - President of Shields Products & Services

OUTLINE OF TOPICS FOR DISCUSSION: There are several factors leading to healthcare not capturing all charges (therefore – claims data and cost reporting data to CMS is understated) for services provided to patients including but not limited to:

1. Cash Flow (reimbursement)
2. Hospital Financials are judged externally on their financial viability from several benchmarks – primary among them are:
    - Overall Accounts Receivable (AR) days
    - Adjustments to Gross Charges (Contractual Adjustments)
    - Reserve for Bad Debt (Patient self-pay portion after insurance payment)
3. Challenges in implementing full-charge capture (and true patient cost accounting) are multifaceted, but the biggest by far is the immediate out of pocket cost to the organization to implement - including but not limited to:
    - Redesign of materials management
    - Redesign of clinical documentation
    - Charge Master (CDM) redesign
    - Abstracting/Coding and Case Management redesign
    - Billing, Claims, and AR Tracking Systems redesign

Of the organizations that Shields has advised/consulted nationally, over 90% do not perform full-charge capture due to the above challenges. There are very few if any immediate positive incentives in implementing full-charge capture. There are significant fears, financial investment costs, painful reveals, and potential negative external perceptions of implementing full-charge capture:

- Fear of CMS/OIG audits and fear of reduced reimbursement and/or denials from other payors.
- Financial investment costs to the hospital are immediate, expensive, and come from the bottom line profitability.
- It is a painful reveal of their current status, some are not willing to rip off the "rose-colored glasses" and prefer to not confront challenges presented – due to executive administrative personal career agendas.
- It "gives off" a negative perception of hospital administration and financial management (admitting full-disclosure of previous practices and benchmarks to boards, banks, foundations, physicians, patients, etc.).

SHIELDS
PRODUCTS & SERVICES

CMS Forum – Cryosurgery

APPENDIX C

08/24/05 10:00a-11:00a

SUMMARY: Claims data provided by hospitals to CMS reflects inconsistent markup and charging methodologies, in order to maintain "status quo" for gross charges to patients. Claims data is not truly reflective of full-charge capture, or accurate chart-to-charging methodology. Due to this, utilizing claims data and cost reporting data on which to base hospital reimbursement is understated in most cases, thus a reduction in reimbursement will significantly impact hospitals' ability to continue to offer this procedure to patients.

6 OF 9 97-0

PHP

Asplen (7)
KANE
SARROW
Hart
BAZELL

8-17-05

File code: CMS-1501-P Partial Hospitalization
Re: Comment to CMS-1501-P Changes to Hospital Outpatient Prospective Payment System and calendar year 2006 Payment Rates-Proposed Rule

I am writing concerning Woodcrest Healthcare, Inc.
Community Mental Health Center

I am requesting the proposed 15% cut for Community Mental Health Center's Partial Program be stopped. Give them a raise for the good work they give each of their patient's.

We would have no alternative place to attend if Woodcrest closes. We live in a rural area and there are no other services when we are Acutely Ill.

I don't like being in a Psychiatric Hospital and that is what would happen if the Partial Programs close.

Again please stop the proposed 15% cuts and give them a ~~30%~~ 3[illegible]% increase.

Sincerely, Melvi R. Price

MASSACHUSETTS GENERAL HOSPITAL

HARVARD MEDICAL SCHOOL

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Gordon J. Harris, Ph.D.
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Director, 3D Imaging Service
Associate Professor of Radiology
Harvard Medical School

1 mnsins
APC | Gen
CCRs

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VIA HAND DELIVERY

September 13, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
(410) 786-7195

Burley
Bittke
Kane
Sarno
Hart
Bazell

Re: CMS-1501-P —Recommendations for Revised Ambulatory Payment Classification for CT Angiography (CTA, currently in APC 0662).

Dear Administrator McClellan:

My colleagues in diagnostic radiology at Massachusetts General Hospital (MGH) and I appreciate the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed rule for the Medicare hospital outpatient prospective payment system (HOPPS) for calendar year (CY) 2006.[1]

CTA is a new technology that was first made possible with the advent of the single slice helical CT in the early 1990s. It became a more robust technology with the introduction of multi-slice CT in 1998 and has become widely used since 1999-2000. CTA offers all of the advantages of showing the vasculature in a 3D format, rather than the 2-dimensional cross-sectional images of CT, without the disadvantages of more invasive and costly procedures such as catheter angiography. CTA can be described as a rapid thin-slice high-resolution CT scan acquired during the dynamic administration of a contrast bolus with appropriate 3D post-processing. The process requires both a CT scanner as well as image processing computer workstations and skilled technicians to process the images. This allows for anatomically detailed 3D views of the vasculature from both outside and inside the vessels.

Under the CY 2006 HOPPS proposed rule, CT Angiography (CTA), which maps to APC 0662 ($304.98), is reimbursed less than Computerized Axial Tomography (CT) without followed by with contrast (w/&w/out), which maps to APC 0333 ($312.16). However, CTA involves all the costs of CT plus the additional work involved in 3D image post-processing. Prior to 2001, this 3D image post-processing was correctly coded additionally under a separate add-on code, CPT # 76375 (APC 0282, which is reimbursed at $98 in CY 2006). Thus, CTA was previously coded as a CT scan PLUS an additional 3D reconstruction charge as two separately coded and reimbursed procedures. When CTA coding was initiated in 2001 to bundle these two procedures into a single procedure code, CTA reimbursement was

[1] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule, 70 Fed. Reg. 42674 (proposed rule published July 25, 2005).

erroneously set equal to CT in APC 0333 (in the absence of prior single procedure claims since CTA was always billed previously as the combination of two separate codes), eliminating all reimbursement for the additional image post-processing. Thus, while CTA involves the combined work of CT PLUS 3D (**clinically CTA=CT+3D**), and from 1996 to 2001, instructions indicated that for **correct coding CTA=CT+3D**, for **CY 2006 HOPPS reimbursement, CTA<CT**, where CTA is reimbursed less than a CT scan alone under the CY 2006 HOPPS proposed rule.

We continue to have concerns that these CTA payment amounts, based on flawed hospital cost data, do not reflect the true cost differential between the two services. CTA is clinically beneficial as a non-invasive and less-costly alternative to procedures such as catheter angiography. In many cases, CTA has replaced catheter angiograms, and this shift represents both a large cost-savings to the Medicare program and a decreased risk to the patient. However, adequate and appropriate reimbursement is required to support the additional resources and work involved with CTA image post-processing compared to CT.

We propose a similar correction for CTA to that implemented this year for diagnostic CT Colonography (CTC-Dx) in response to our recommendations to the APC Advisory Panel January 25, 2005. Prior to implementation of the new CTC-Dx bundled code, CTC-Dx was previously billed as a combination of three exam codes: CT abdomen PLUS CT pelvis PLUS 3D (**CTC-Dx=CT(Abd)+CT(Pelv)+3D**). CTC-Dx also involves the additional costs and work of insufflation, prone and supine scanning, and in about half of these exams, contrast is used. In the 2005 HOPPS rule, CTC-Dx (CPT 0067T), as a newly bundled and newly coded procedure, was placed into the same APC as CT non-contrast exams (APC 0332, reimbursed in 2006 at $193), thus, for **CY 2005 HOPPS final rule, CTC-Dx=CT**. This APC placement was made erroneously, without any prior claims data (as was also done in 2001 for CTA), since CTC-Dx was always billed previously as a multiple-claims procedure, and CMS does not use multiple-claims in calculating costs. Thus, we indicated to the APC Advisory Panel that it was inappropriate to place CTC-Dx in the same APC as a single CT non-contrast exam. In response to favorable recommendations by the APC Advisory Panel to our comment, CMS has moved CTC-Dx from APC 0332 ($193 in 2006) to APC 0333 ($312 in 2006), an increase of $119 in reimbursement. Thus, CMS acknowledged that the placement of CTC-Dx in APC 0332 underrepresented the relative costs of the procedure, and moved CTC-Dx out of APC 0332 and into the higher reimbursement of APC 0333.

CTA has had similar APC placement issues as occurred with CTC-Dx. CTA was created in 2001 as a newly bundled combination of two codes, CT w/&w/out contrast PLUS 3D, but was initially erroneously placed in the same APC as CT w/&w/out, again without reference to prior claims since these involved multiple-procedures. Thus, CTA and CTC-Dx had almost identical APC placement problems initially. Subsequently, in 2003, in response to our comments indicating that CTA was clinically distinct from CT and involved added costs, CTA was moved into the new APC 0662 in order to attempt to capture the added relative costs of CTA relative to CT. However, as the only procedure in the new APC 0662, the reimbursement is now actually less than CT w/&w/out (due to factors detailed below). We therefore recommend that CTA be moved from APC 0662 (reimbursed $304.98 in the 2006 proposed rule) to an APC of related angiographic imaging procedures that reflect the cost of CT PLUS 3D (APC 0333 is $312, PLUS APC 0282, which is $98). Some alternative APCs for CTA include Level I Angiography/Venography (APC 0668, $384), MRI/MRA w/ contrast (APC 0284, $379), or MRI/MRA w/&w/out contrast (APC 0337, $520). These APC categories could be amended to include CTA in the descriptor, and the combinations would be appropriate since these are all various forms of angiographic imaging. Such a change in APC classification for CTA would finally correct the reimbursement problems

that have plagued CTA since its bundling into new codes in 2001, and would be a consistent solution to that implemented under HOPPS for CTC-Dx. Both of these similar reimbursement issues (CTC-Dx and CTA) were strongly supported by the APC Advisory Panel as noted in this comment.

APC ADVISORY PANEL RECOMMENDATIONS, CY 2005 RULE COMMENTS

We appreciate the opportunity that CMS granted us to present the CTA issue to the APC Advisory Panel on September 2, 2004. During the discussion that followed our presentation, the Advisory Panel expressed support for our concerns and recognized this issue as a serious problem that should be addressed and recommended to CMS that this be resolved. The Advisory Panel recommended that we schedule a follow-up meeting among CMS, ACR and other interested parties to determine the best potential solution. In response to the Advisory Panel's recommendations, I met with Herb Kuhn of CMS in Washington, DC on September 27, 2004, and discussed this issue with him. On October 6, 2004, I met together with ACR and CMS in Baltimore to discuss proposed solutions with Cindy Reed and colleagues from CMS. Unfortunately, at these meetings CMS staff indicated that they could not give feedback to us regarding our proposals since they were within the comment period. We submitted our recommendations as comments to the proposed rule. In addition to the support of the APC Advisory Panel, our comments were also reflected in those from the American College of Radiology (ACR), NEMA, and General Electric HealthCare.

We demonstrated in our comments that only 40% of hospitals submitting claims for CTA and CT had CTA charges greater than CT charges – most hospitals charged LESS for CTA than CT, a logical inconsistency since CTA involves all the costs of CT plus all the costs of image post-processing, billed separately under CPT # 76375 prior to 2001. We proposed that CMS adjust the reimbursement for CTA to be equivalent to that of CT PLUS 3D, as it was originally billed, and similarly to the correction made under the Medicare Physician Fee Schedule for CTA in 2003 as summarized below:

Clinically, CTA=CT+3D

	Prior to 2001	**2001-2002**	**2005-2006**
HOPPS	CTA=CT+3D	CTA=CT	**CTA<CT**
MPFS	CTA=CT+3D	CTA=CT	**CTA=CT+3D**

While we understand that it is neither uncommon nor unreasonable for procedures to be reimbursed below their costs under the Medicare HOPPS, we are concerned because CMS sets the relative weight for each service by assuming that a hospital's charges for services will reflect, at least in relative terms, the full resources used by that hospital in providing that service.[2] As our analyses of the HOPPS claims from hospitals that billed for both CT and CTA show, the majority of claims for CTA do not represent the full resources used for CTA relative to CT. Therefore, we expressed concern that the claims data set should not be used as the basis for setting CTA reimbursement in CY 2005.

[2] CMS anticipates "that a hospital's charges on particular services reflect, at least in relative terms, the hospital's resource use in providing that service." (67 *Federal Register* 52094)

CMS rejected our comments in the final rule for CY 2005 (69 Fed. Reg. 65722, published November 15, 2004), in which CMS responded by indicating that, "although we understand the commenters' points of view and appreciate the comprehensive analyses they shared with us, we cannot identify any action that would be appropriate for us to take. As the commenters are aware, we rely on hospital claims data to set payment rates and have made clear our intent to rely solely on those claims by CY 2007." Thus, it seems that CMS is indicating that regardless of how flawed claims data may be proven to be for a particular new procedure, there is no opportunity to override these methods, even if the methodology for a particular new procedure or perhaps many new procedures is shown to be inaccurate. This is a particularly troublesome position, which adversely impacts on services like ours that are dependent on CTA reimbursement to support our ability to provide CTA services to patients in lieu of more invasive and expensive procedures like catheter angiography, or to companies like Medical Metrx Solutions, Inc., which uses the G0288 code for pre- and post-operative planning of aortic aneurysm repair (G0288 reimbursement was cut by 57% in 2005 from 2003). Thus, even with clear evidence of methodology problems and claims data flaws, there appears to be no recourse, other than to encourage hospitals on a case by case basis to alter their charges (see details below of methodology issues). CMS indicated that they cannot fix this issue similarly to the MPFS correction because "the OPPS system, unlike the Medicare Physician Fee Schedule, relies on historical claims data to develop relative costs of service." Thus, although this problem was fixed two years ago under the MPFS, CMS rejected a similar solution for HOPPS. **However, although CMS did not accept any of our proposals for CY 2005 to fix the CTA reimbursement problem, we feel that we have determined an alternative proposal that is consistent with Medicare methodology, and in fact was applied in 2005 to fix a similar issue with APC placement for Diagnostic CT Colonography.**

They further argued that, "based on the available CPT codes for CTA, we would not expect any current utilization of CPT code 76375 to be for CTA post-image processing, unless there was no appropriate CTA code to describe the body region imaged. We believe this would be rare." This response from CMS completely misses the issue. By definition, there is no use of CPT code 76375 with CTA; there is an edit against using these together. However, the issue of concern is that CTA was originally correctly coded between 1996 and 2001 as CT plus 3D – two separate codes to cover the costs of CT plus 3D post-processing. New CTA codes were created in 2001 to combine CT PLUS 3D – these code descriptors indicate CT without followed by with contrast scanning, PLUS image post-processing. Thus, the image post-processing previously correctly billed under a separate add-on code was incorporated into the new CTA codes in 2001 to cover the resources from two separate procedure codes combined into one. The argument by CMS that there is no current utilization of 76375 with CTA is a re-statement of the coding policy. This is not the problem. The issue is that CTA involves added post-processing effort, equipment, staff time, resources, etc. These costs were estimated based on the ACR cost-survey data at $138, and were previously partially covered by CPT 76375, which pays $98. This reimbursement for image post-processing has been entirely, 100% eliminated from CTA reimbursement, as CTA is now reimbursed less than CT.

HOPPS COST-TO-CHARGE PROBLEMS FOR PROCEDURES INTRODUCED AFTER 2000

During our presentation to the APC Advisory Panel in September 2004, we were asked to explain why claims for CTA were less than those for CT at the majority of hospitals. This leads to a discussion of a

broader, fundamental methodological problem with applying cost-to-charge ratios (CCR) to charges for new procedures introduced after HOPPS was implemented in 2001. CMS methodology under HOPPS involves determination of median costs based on a conversion of each hospital's charges multiplied by the cost-to-charge ratio of the hospital department. Prior to HOPPS' introduction in 2000, hospitals were reimbursed at a proportion of charges, often in the range of 20%-30% of charges. Thus, hospitals' charges were inflated often by a factor of 3-5 times the reimbursement amounts, in order to recoup appropriate reimbursements. This charge inflation resulted in self-pay patients being unfairly penalized and required to pay artificially high rates for health care.

This charge inflation problem was a serious concern that the introduction of HOPPS was partly intended to remedy by unlinking charges from reimbursements to hospitals. Under HOPPS (hospital outpatient PROSPECTIVE payment system), many hospitals assume that payments are prospectively determined and that "charges no longer matter". However, the old cost-to-charge ratios are still used by CMS under HOPPS to calculate the "imputed cost" of procedures based on charges multiplied by the cost-to-charge ratio. Since all but a few procedure codes pre-date 2001 and were active prior to HOPPS, these cost-to-charge ratios may work reasonably well for older procedures with inflated charges instituted before HOPPS. These charges were inflated by hospitals to reflect the old payment ratios and reimbursement methodologies, and these high charges remain in place, as do the associated low cost-to-charge ratios. Thus, the cost-to-charge ratios for older established codes relative to charges are often reasonable estimates of appropriate reimbursement.

The problem arises with new procedures instituted in 2001 or later, particularly procedures such as CTA (and others such as G0288) that are in new APC classifications not weighted by other older codes. Many hospitals no longer inflate charges for new procedures in the interest of public fairness. It is no longer considered necessary to inflate charges to get reimbursed, and it is considered unfair to inflate charges, which would penalize self-pay patients. Thus, in good conscience, hospitals no longer inflate charges by the old cost-to-charge ratio formula of pre-HOPPS days, in the interest of the public good. This is appropriate policy and should be encouraged.

Unfortunately, HOPPS methodology penalizes new procedures as follows. Hospital cost-to-charge ratios remain low according to the inflated charge markups previously applied under the old pre-HOPPS system, and most procedures retain these high charge mark-ups of 3-5 times reimbursements, thus cost-to-charge ratios remain low. Charges for new technologies and new procedures instituted post-HOPPS are set with less charge-inflation by hospitals, often at 1-2 times the reimbursement rate. In the recent GAO report on Medicare, *"Information needed to assess adequacy of rate-setting methodology for payments for hospital outpatient services,"* (GAO, September 2004), problems were clearly identified with CCR methodologies as related to variations in hospital charge setting practices. The GAO found that only 29% of hospitals used cost data in setting charges, while a slightly higher percentage used CMS reimbursement rates as a basis for setting charges (instituting a circular system of reimbursement setting, charges, and imputed cost calculations). Unfortunately, this system and methodology penalizes new procedures when the hospitals no longer inflate charges in proportion to the department wide CCR. In the CMS response to the GAO report, CMS indicated that CT departments had the lowest CCR overall at 0.12, indicating that hospitals would need to inflate charges for new CT procedures such as CTA by 8 times their actual costs to have an "imputed cost" that reflected actual costs. Thus, when CMS applies the old cost-to-charge ratios to new procedures, the calculated "imputed cost" can become severely deflated relative to older technologies. Thus, new technologies, which may be better, faster, cheaper, and safer than older technologies, are

severely penalized by hospitals' efforts to set charges less aggressively for new procedures under HOPPS. We believe that this is the principle reason that most hospitals charge less for the new CTA codes than the older CT codes. Some hospitals charge almost four times more for CT than for CTA, even though CTA involves additional work relative to CT. This problem has also already plagued several other new technologies, including digital mammography, magnetoencephalography (MEG) and aortic aneurysm planning and surveillance (G0288). Furthermore, this problem will likely adversely impact reimbursement for other new codes such as the new PET and PET/CT codes once the claims data for these new procedure codes are put through the cost-to-charge ratio calculations in a few years, and if these are placed in new APCs alone.

For CTA, CMS has thus far rejected our proposals to date to correct this problem. However, we feel that we have developed a new approach to solve this problem for CTA reimbursement that will not require CMS to change their methodology for determining reimbursement rates, and therefore, we hope, our new proposal will be an acceptable way to solve the CTA reimbursement problem. Furthermore, the proposed approach was similarly applied to correct an analogous problem for reimbursement and APC classification of diagnostic CT Colonography (CTC-Dx), as detailed above. The proposed approach could also be applied to address similar CCR methodology issues for other new procedures introduced post-HOPPS after 2001.

Unfortunately, unless these issues are corrected, CMS will continue to punish new technologies by using the old cost-to-charge ratios to calculate reimbursements. This will either discourage adoption and dissemination of new technologies that could replace more invasive and expensive older technologies, or encourage hospitals to return to a bygone era of charge inflation for new technologies on a national level if new technologies are to have a chance of financial survival. Under the current system, new technologies must either encourage charge inflation or suffer severe reimbursement deflation, and corresponding inability to compete economically. Neither of these options is attractive or was envisioned as a consequence of HOPPS, but this is what is occurring.

RECOMMENDATIONS FOR CMS TO CONSIDER

The hospital-submitted charges for CTA are unreliable, inconsistent, and inaccurate, reflecting the problems new technologies face with cost-to-charge methodologies as detailed above. Since CTA stands alone in an APC category created solely for CTA, CTA reimbursement suffers from this methodological flaw. However, we feel that there is a simple solution to this problem for CTA, and which could be applied to other new procedures as well. We recommend moving CTA to a related APC that has reimbursement appropriate to the work of CT PLUS 3D, as CTA was originally designed. This will allow CMS to continue to use CTA claims as part of a broader APC, and the weighting of CTA with other procedures will help to offset the impact on CTA reimbursement of the CCR methodology flaws, and will finally address this issue, as recommended by the APC Advisory Panel.

Thus, based on the comments above, we propose the following:

- **We propose to move CTA from APC 0662 ($304.98), into another APC with other related angiographic imaging procedures at a reimbursement level more appropriate for the work of CT w/&w/out ($312.16) plus 3D ($97.73). We have identified three candidate APC categories:**

- **APC 0668 ($384.17): Level I angiography/venography**
- **APC 0284 ($379.31): MRI/MRA w/ contrast**
- **APC 0337 ($519.59): MRI/MRA w/&w/out contrast**

These APC category descriptors could be revised to include CTA, for example, "MRI/MRA and CTA", or "Level I angiography/venography and CTA."

We futher recommend that CMS, ACR, and other interested parties (AHA, industry, Congress, etc.) set up a discussion team to investigate and report back with recommendations on how to address CCR methodologies for new technologies introduced since implementation of HOPPS.

Perhaps through a multi-disciplinary team approach, we can address, not only the CTA reimbursement issue, but the underlying methodologies that will impact other new procedures such as PET/CT, magnetoencephalography, aortic aneurysm planning, etc.

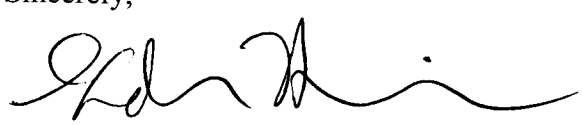
CONCLUSION

We believe our historical and data-driven analyses tell a strong story that the hospital coding and charges for CTA services are not reliable indicators of relative costs. Therefore, we strongly urge CMS to consider moving CTA out of APC 0662 for CY 2006, and move CTA to an alternative APC category that reflects the relative work of CT PLUS 3D costs, in order to appropriately reflect the additional costs associated with performing this important service. This solution to the CTA reimbursement issue would not require any change in CMS methodology, and is a consistent approach to the correction that was applied in 2005 for diagnostic CT Colonography (CPT 0067T). Failure to adequately pay providers for the additional costs of performing CTA will result in diminished resources for my department at MGH and other radiology departments throughout the country that process CTA exams. CTA is clinically beneficial as a non-invasive and less-costly alternative to procedures such as catheter angiography. In many cases, CTA has replaced catheter angiograms, and this shift represents both a large cost-savings to the Medicare program and a decreased risk to the patient. Adequate and appropriate reimbursement is warranted, and will allow hospitals to continue to provide this valuable service.

* * * * *

I realize that you may require more information, which I would be happy to provide on request. If you have any questions regarding these comments, please do not hesitate to contact me at 617-726-9464.

Sincerely,



Gordon J. Harris, Ph.D.
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ONCURA

APC/D-D
Imaging
B-Therapy

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Heygstee
Burley
Levi
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Sarow
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Brzell

September 13, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

VIA: HAND DELIVERY

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P

Dear Administrator McClellan:

These comments are submitted on behalf of ONCURA,[1] a leading manufacturer of state-of-the-art medical products and systems that employ novel hypothermic surgical technologies to destroy cancerous tissues. Our products include cryoablation systems, which offer highly effective and minimally invasive therapies for prostate and kidney cancer. Additionally we provide brachytherapy source products for the treatment of cancer.

We appreciate the opportunity to comment on the proposed rule published by the Centers for Medicare & Medicaid Services ("CMS") on July 25, 2005 *Federal Register* notice which proposes changes to the Hospital Outpatient Prospective Payment System (the "OPPS") for 2006. See Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, Vol. 70, No. 141 (July 25, 2005) (the "Proposed Rule

We wish to comment on the following specific APC assignments related to cryotherapy and brachytherapy:

APC 651 (CPT 77778) - *Interstitial Radiation Source Application; Complex*

We also wish to comment on the following policy issue:

Device-Dependent APCs – Required Use of "C" Codes for Devices

We set forth more detailed comments below.

* * *

[1] ONCURA was created in July 2003 by the merger of Amersham's brachytherapy business with Galil Medical Ltd's urology business.

HOPPS POLICY COMMENTS

I. PROPOSED REQUIRED USE OF "C" CODES FOR OTHER DEVICE DEPENDANT PROCEDURES

Oncura supports CMS's proposal to require hospitals to bill device-dependent procedures using the appropriate "C" codes for the device. Oncura recommends that CMS consider expanding their proposal to require appropriate "C" codes for ***all*** device-dependent APCs.

Specifically, Prostate Brachytherapy requires the use of medical devices "radioactive sources (seeds)" and we suggest that brachytherapy source "C" codes be required for APC 651. We believe that limited mandatory "C" coding is more of an administrative burden to hospitals and clearly causes confusion. Our belief is based on our experience in 2003 with our hospital client's lack of understanding that not all C-Codes had expired. Further, once the mandatory C-Code provision was implemented in April 2005 for the limited set of device dependant procedures identified by CMS, even though we had put forth a significant education effort with the hospitals, we were inundated with inquiries as to why the CMS FI's were returning claims for procedures performed on or after April 1, 2005 following the CCI edit requiring C-Codes for our cryosurgery product line. ***Oncura supports expanding the proposed policy to include all device-dependent APCs in order to promote "correct coding" and improve the quality of the claims data.***

II. Brachytherapy

A. APC 651 – CPT 77778 Complex Interstitial Radiation Source Application

Table 2 Comparison of 2005 vs. Proposed 2006 HOPPS Payment Rates for Brachytherapy APCs

APC	CPT Codes	2005 Payment	2006 Proposed Payment	Percentage Change from 2005 to 2006
651 Complex Interstitial Radiation Source Application	77778	$1,248.93	$720.71	-42.3%

Background

APC 651 includes one CPT code, 77778 *Interstitial Radiation Source Application; Complex*. This interstitial brachytherapy procedure is one of the two main procedure codes used to code prostate brachytherapy. The aforementioned code is also used to code other complex interstitial brachytherapy procedures. The 2006 proposed payment for APC 651 is published as $720.71, which is a 42.3% reduction from the current payment of $1,248.93.[2]

In 2004, there were 11,963 claims that contained CPT code 77778, however, CMS based the 2006 proposed payment on just 342 claims or approximately only 2.8% of outpatient claims. The extremely low volume of claims used for rate-setting is troubling. Based upon our analysis, CMS did not use "correctly coded" claims to set the 2006 proposed rates for CPT

[2] See Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, Vol. 70, No. 141 (July 25, 2005) (the "Proposed Rule").

77778. If CMS had used claims that contained CPT 77778 and at least one brachytherapy device "C" code, the median cost increases by approximately 18% to $864.54. In past years, CMS has used only "correctly coded" claims to determine payment rates for certain services and we recommend that they do so for APC 651 for rate setting in 2006 for this service.

Since the inception of HOPPS in 2000, the payment policy and coding for important components of prostate brachytherapy have changed numerous times and the payment rates have been very unstable. The hospital claims data for prostate brachytherapy has fluctuated considerably. The proposed decrease in the payment for APC 651 is significant, and this is part of an ongoing concern that considerable problems exist with the accuracy and/or interpretation of CMS's data for prostate brachytherapy procedures. Given the significant changes that have occurred on an annual basis since 2000 in coding of prostate brachytherapy services, devices and supplies, the hospitals have faced a number of challenges in correctly coding and reporting charges for prostate brachytherapy procedures. Oncura is an active member of CAB (Coalition for the Advancement of Brachytherapy)[3]. CAB retained Christopher Hogan, Ph.D. of Direct Research LLC [4] to perform an independent analysis of the 2004 claims data that formed the basis for the 2006 payment rates. Dr. Hogan's analysis of the claims data specific to CPT 77778 appears throughout our correspondence and is presented in Tables 3 through 5.

CMS continues to rely exclusively on single procedure claims to establish payment rates for the hospital outpatient APCs. This approach excludes more than 97 percent of the complex interstitial brachytherapy claims from the calculation of the proposed payment rates for APC 651 (see table 3).

Table 3 Comparison of All Claims vs. Single Procedure Brachytherapy Claims

APC	Total Number of All Claims	Total Number of Single Claims	Percentage of Claims Used for Rate-Setting
651 Complex Interstitial Radiation Source Application	11,963	342	2.8%

The fact that CMS is using such a small percentage of total claims to establish CPT 77778 rates heightens the need for CMS to ensure that non-representative claims do not distort the payment rates. Claims that had both the brachytherapy procedure and a brachytherapy source "C" code had median costs that were 9 percent to 34 percent higher than the average of all single-procedure claims for the APC. This suggests that CPT 77778 should be on the list of device dependant procedures and a "correct coding" screen is necessary to ensure more appropriate and accurate payment rates for APC 651.

Correctly Coded Claims

Mr. Hogan's report prepared for CAB undertook an analysis of the 2004 claims to determine what percentage of all brachytherapy claims and single procedure brachytherapy claims were "correctly coded," which included both a brachytherapy procedure code and a brachytherapy source device "C" code (see table 4) For this analysis, a single-procedure claim

[3] CAB – The Coalition for the Advancement of Brachytherapy. CAB was organized in 2001 and is composed of the leading developers, manufacturers and suppliers of brachytherapy devices, sources and supplies.

[4] Christopher Hogan, Ph.D. President of Direct Research LLC

was "correctly coded" if the original claim from which it was created had the proper brachytherapy source "C" code on the claim.

Table 4 Percentage of "Correctly Coded" Brachytherapy Claims

APC	Total Number of All Claims	Percentage of "Correctly Coded" Claims	Total Number of Single Claims	Total Number of "Correctly Coded" Single Claims	Percentage of "Correctly Coded" Single Claims
651 Complex Interstitial Radiation Source Application	11,963	86%	342	181	52.9%

Additionally, a comparison was made of the median costs of all single procedure claims compared to the median costs of "correctly coded" single procedure claims (see table 5)

Table 5 Comparison of Median Cost of Single Claims vs. "Correctly Coded" Single Claims

APC	Median Cost of Single Claims	Median Cost of "Correctly Coded" Single Claims	Percentage Difference of Median Cost
651 Complex Interstitial Radiation Source Application	$732.86	$864.54	18.0%

Worth noting is that the criteria used for the analysis properly removed the costs of the brachytherapy source ("C" code) line items before calculating the total packaged costs of APC 651. This should be clear, as our median costs for all claims is quite close to the median as published by CMS. So, the higher costs of the correctly-coded claims is not due to the (improper) inclusion of the source costs in the median calculation, but reflects the impact of selecting claims from hospitals who carefully and fully code the charge data.

Recommendation for CPT 77778 (APC 651) Complex Interstitial Radiation Source Application

Oncura recommends CMS use only "correctly coded" claims to adjust the final 2006 relative weights for APC 651. CMS should also require mandatory hospital coding of the appropriate brachytherapy source "C" codes for brachytherapy procedure CPT 77778 (APC 651). CMS should also consider developing alternative methodologies to utilize single and multiple procedure claims for rate setting purposes so that a higher number of claims for CPT 77778 may be included.

Payment rates for brachytherapy must be stabilized. A 42.3% payment reduction is very significant, and as CMS notes in the proposed rule, reductions in excess of 15% "may be problematic for hospitals that provide the services contained in this APC," and may affect beneficiary access to this important treatment for prostate cancer. Medicare beneficiaries have the right to have access to the available treatment options for prostate cancer Utilizing only "correctly coded" claims and applying the "device-dependent" adjustment factor to APC 651 will help address these concerns and will limit the proposed reduction in 2006 payment for complex interstitial brachytherapy.

VIII. CONCLUSION

ONCURA appreciates the opportunity to submit comments on the Proposed Rule, and we are eager to provide CMS with any information or clarification that would enable the agency to ensure Medicare beneficiaries continued access to prostate brachytherapy. We recognize that a system as complex as HOPPS will continue to encounter challenges for specific types of services, including brachytherapy. If CMS staff would like to discuss these issues in greater detail, or if we may be of any further assistance, please do not hesitate to contact me or you may also contact Lisa Hayden at (703) 948-7685.

Sincerely,

Jim McGlone (JM)

James McGlone
President/CEO Oncura

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American Academy of Otolaryngology – Head and Neck Surgery

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September 12, 2005

APC / D-D
Pymt / Devices

Heygster
Levi
Kane
Sanow
Hart
Bazell

Mark McClellan, MD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Dear Dr. McClellan-

On behalf of the American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS), I am pleased to offer our comments on the proposed rule relating to the 2006 Medicare hospital outpatient prospective payment system, as published in the July 25, 2005 *Federal Register*.

The AAO-HNS represents approximately 12,000 physicians in the United States who diagnose and treat disorders of the ears, nose, throat, and related structures of the head and neck. The medical disorders treated by this specialty are among the most common that afflict all Americans, old and young, including upper respiratory infections, hearing loss, swallowing disorders, rhinological disorders, and head and neck cancer.

We are concerned about the proposed payment rate for cochlear implants, CPT code 69930/APC code 259. Under the proposed rule, the payment for this procedure would be decreased from $25,307 to a proposed rate of $21,643.31. A decrease of reimbursement this significant, combined with other challenging economic factors for hospitals, would force them to re-consider the financial viability of their programs. As a result, it would limit the access of Medicare beneficiaries to hospitals who would be willing to provide cochlear implant services and thereby foster continued medical disability.

We understand that the Lewin Group has conducted a study of device costs for cochlear implants, and discovered that the cost of the device has not decreased in the past year. Their analysis suggests a more appropriate reimbursement rate of $27,192. We ask CMS to consider the data analysis performed by the Lewin Group, and recalculate the payment rate for cochlear implants based on their findings.

We appreciate all the work CMS has done to date to ensure accurate reimbursement for cochlear implants, and to ensure access for Medicare beneficiaries to this very important service. Thank you for taking the time to consider our comments on this matter.

Sincerely,

David R. Nielsen MD

David R. Nielsen, MD, FACS
Executive Vice President and CEO